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HANDBOOK FOR CONTAMINATION CONTROL ON THE APOLLO PROGRAM

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PREFACE

The advances made in the nation's space programs have resulted in increased emphasis being placed on cleanliness by both industry and Government agencies. The ever expanding need for cleanliness has developed into a highly organized technology in contamination control. It is essential that this technology be fully utilized to meet the need for the precision, safety, and sophistication of articles involved in the Apollo space program. Many of the costly delays and failures on previous space projects have made abundantly clear the severe consequences of inadequate contamination control.

The information contained in the handbook is of three types. The first type is general and philosophical in nature. The second type includes technical and operating data. The third type of information consists of reference material that will be useful in preparing effective contamination control programs.

Text material was obtained from many sources, including attendance at symposiums, review of industry and Government documents, and discussions with recognized authorities in the field of contamination control.

It is believed that this handbook will help to achieve the fullest utilization of current contamination control technology on the Apollo program.

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SECTION 1

INTRODUCTION

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INTRODUCTION

Experience on past space programs has shown that an entire mission can fail because of contamination. This contamination may be anything from an accumulation of tiny, practically invisible dust particles to gross chunks of solder, lubricants, and debris from the fabrication processes.

For most purposes any kind of foreign material is considered contamination. However, different industries have different problems and a troublesome contaminant in one industry may be of little or no consequence in another. In the manufacture of space hardware, particulate and fluid type contaminants are of primary concern. For this reason, this handbook places emphasis on their control. Other types of contaminants may be encountered; however, in general, many of the practices and principles employed to control particulate and fluid matter are applicable to other types of contaminants. Consequently, the philosophy and discipline for contamination control presented in this handbook should apply in most circumstances to most types of contaminants.

In any industry or for any product, the concept of contamination control must be thought of as an all encompassing program effort. To be successful, the effort must begin during the design or engineering phase of a program and continue through to the end use of the item or until completion of the mission. This concept expands the earlier limited view of parts cleanliness to the present broad scope of a complete technology that includes control of factors in design, facilities and equipment, testing and measuring techniques, personnel selection and training, factory procedures, quality control provisions, and nearly all other features of an industrial activity.

Frequently, the tendency is to equate contamination control technology with clean room design and operation. However, it is fundamental that one does not equal the other and it is essential that such an approach be carefully avoided. The clean room or controlled environment facility is only a single element in a contamination control effort. Unquestionably, the clean room is a very important and useful tool in contamination control and usually (but not in all cases properly) involves the largest item of capital investment. In addition, the clean room is usually the most obvious manifestation of a

contamination control program. This handbook discusses in detail the basic factors in the design and application of a clean room. The clean room is emphasized because of its importance, its frequent misuse and the large capital expenditure involved.

A complete contamination control program must contain several elements, of which the following are of primary concern:

a. Design with contamination control in mind.
b. Achieve the level of cleanliness required by design.
c. Verify the level of cleanliness.
d. Maintain the level of cleanliness.
e. Provide a means to indicate violation of cleanliness.
f. Implement quality control procedures to insure the integrity of the effort.

The need for contamination control is determined at the design level for a part or a system. It is the need for precision, the complexity and sophistication of the design, and the environments and conditions of use that determine the degree to which contamination control must be employed. The responsibility for specifying cleanliness requirements clearly rests with the designer. He must bring together all the factors that influence the need for cleanliness and determine the degree of cleanliness and control that will assure the success of the design. Once the design activity has established the need for, and the level of, cleanliness the responsibility for achievement is passed on. Of course, like all other design considerations, there must be a feedback or information loop among design, fabrication, applications, quality control, etc., to assure that all factors are considered and that theory is reconciled with practice.

After the design has been established and the need for cleanliness has been determined, the contamination control program is developed to fit specific requirements. The next consideration is to evolve the processes for cleaning, fabrication, handling, test, etc. The facilities and equipment for processing and fabrication are selected to produce the articles of design. Those responsible for contamination control concurrently develop a plan to include appropriate techniques into the equipment, facilities, and processes. The plan may involve simple well-known cleaning methods, conventional production facilities, and standard tools, methods, packaging, etc. On the other hand, for high levels of product cleanliness, highly developed precision cleaning processes may be employed, specially constructed clean rooms might be installed, and sophisticated testing and monitoring techniques specified. Highly disciplined personnel may be needed; special packaging materials and techniques are usually necessary; and the list of specialty items may be extensive.

All these aspects are directed toward getting the part clean and keeping it clean to that level that will assure success. It is a beginning-to-end effort. Quality control organizations play a key role in this entire scope. They must see that the contamination control plan is developed, that it is implemented, that it is maintained, and that it is verified. Further, any failure of the system or breakdown of the chain must not go undetected.

SECTION 2

DESIGNER'S ROLL AND RESPONSIBILITY FOR CONTAMINATION CONTROL

SECTION 2

DESIGNER'S ROLE AND RESPONSIBILITY FOR CONTAMINATION CONTROL

2.1 DESIGN PHILOSOPHY

Any discussion of the designer's role in a contamination control program can only be academic. However, it is fundamental that consideration of contamination control for a given product begin during the design phase. After all, the features of design determine the need for contamination control. It is the precision, complexity, material compatibilities, sophistication, purity, susceptibility to environment and all other factors that create and influence the sensitivity of the product to the conditions that are encountered. The designer (design activity) deals with all these factors in developing the design of the product. Only he can predict the relative influence of various kinds of contamination on the product.

One of the questions often heard during a discussion of contamination control technology is "How clean is clean?". This appears to be a pertinent question; however, the term "clean" by itself is indefinite in meaning and has different values in different contexts; it means different things to different people relative to their interests. Clean in terms of bacteria or fungi is not necessarily the same in terms of chemical or particulate matter. The question as stated clearly asks for a definition of the word clean. Since it is the designer who must consider all influences on the proper function of the design, the designer has the responsibility for defining the term "clean" for his product. Obviously, cleanliness is related to the product and has only vague meaning, unless it is used in context with the product.

The question of "How clean is clean?" may be rephrased into "What is the contamination sensitivity of this item (part, material, process, system)?" Within this concept, it is an acceptable question and should be taken as a challenge by the designer for an answer.

The designer may be inclined to take the attitude of "make it and keep it as clean as possible." However, such an attitude shows that fair consideration was not given to the contamination sensitivity and that the designer is not meeting his responsibility. To impose such an arbitrary design requirement may cause the product to be suspected of being so highly contamination sensitive as to be unreliable and it would lead to the question of whether the design can be improved to be less contamination sensitive so that higher reliability may be expected. Although freedom from all foreign material may be

desirable from the designer's standpoint and vastly simplify his task, such an ultimate condition cannot be achieved. The design must be realistic in recognizing this fact and make the proper allowance.

In practice, an extremely high degree of freedom from foreign material may be necessary and techniques can be developed by using present technology to accomplish such a requirement. The designer must keep in mind, however, that as contamination sensitivity increases, costs increase, delays increase, fewer sources of production capability are available, and the reliability of the product is reduced.

2.2 DESIGN ASPECTS

The designer may consider contamination from two aspects: first, exposure to contaminating sources during the functioning or use of the product from either the environment in which it operates or from the creation or generation of contaminants by the operation of the device or parts of the device; second, the designer must consider the effects of contamination during the fabrication, assembly, test, installation, etc. The first case, exposure to contaminating sources and the generation of contaminants during the operation of the device, is beyond the influence or control of any manufacturing activity. The design must allow for and accommodate the level of contamination within which the device must operate or to which it will be exposed during operation.

It is purely within the realm of design analysis and development to include features that either allow or offset the effects of such operating contamination. Typical examples of some of the measures in use are the getter in electron tubes to absorb contaminants from the elements as they outgas during operation; many components and assemblies are sealed in cans or potted in plastic to exclude moisture or corrosive atmospheres; and in some cases protective finishes and coatings are used to protect critical surfaces. Besides this, the design engineer designates clearances and tolerances and specifies materials that will permit operation in an adverse environment. It is important to consider contamination generated by the operation of parts such as pumps, valves, etc. Filters are often used in fluid service to remove contaminants as they are generated in the fluid system. In this case, it should be noted that filters are not a cure-all for fluid borne contaminants and that other factors must be taken into account during design to reduce the occurrence of contamination.

The measures that the designer may take to assure proper operation at an expected level of contamination should not be considered contamination control, for these are

simply application of good analytical and developmental principles to the design. On the other hand, the designer is often faced with an entirely different set of conditions that will create inherent sensitivity of the product to contamination prior to its use. This presents different problems that go beyond the usual role of the designer. Then, there is a need to provide a manufacturing, test, storage, etc., capability that can manage the level of contamination and insure the integrity of the finished product.

The nature of the product will often make it susceptible to degradation from various forms of contamination before its use. For instance: high-resolution photographic film is well known to be degraded by particles of material as well as by the chemical action of some common gaseous environment; in many mechanisms close tolerances and tight clearances require freedom from dust particles that are found in normal atmosphere; and many of the recently developed electronic devices rely on extreme control of material purity to achieve certain qualities. An unlimited number of conditions exist whereby contamination can create a problem. Also, in practice there is a limitless number of variables that may come into play; consequently, each product of a unique design presents a unique problem. One set of variables will be applicable to each design of each product, and will determine the contamination control program to meet that particular need.

2.3 DESIGNER'S FUNCTION

As pointed out earlier, the concept of contamination control is a beginning-to-end effort. The total program is made up of several elements. The combination of elements determines that the contamination control program will be different for every product, depending upon the degree and type of contamination sensitivity and the manufacturing sequence involved. Many similar programs may be developed with only slight variations in detail. However, it is these variations in detail that can mean success or failure for each attempt.

The designer cannot hope to see and appreciate the full scope of activities involved in manufacturing, process control, test, storage, etc.; nevertheless, all these factors enter into successful contamination control. The designer must be aware that any activity at any stage in an industrial operation can result in a contaminated part if adequate discipline and control are not in force.

Because the designer knows that he cannot control or guarantee freedom from contamination prior to use of the product, he should make every effort to see that his design is the least susceptible to all forms of contamination. He should attempt to avoid using parts or materials that create contaminants or are sensitive to contaminants during manufacturing, assembly, etc.

In addition, a designer should become familiar with the fundamental operations involved in cleaning. With these in mind, he should attempt to avoid using parts which generate and entrap contamination during assembly. An example of such a component is a fluid line coupling with pressure fitting sleeves. No matter how clean the details are, contamination is generated during the assembly operation. It is unlikely that this type of contamination will be removed by final cleaning and hence could be a potential hazard if the contaminant is released at a later date. These considerations may involve a design review with emphasis on contamination sensitivity. In any event, such considerations will provide the basis for establishing the contamination sensitivity of the product.

This is not to say that the designer can accurately predict the point at which contamination will become a problem. This may or may not be possible, but the usual situation will be that the design activity will identify features that are susceptible to the various forms of contamination and will stipulate that the integrity of these features are to be assured until the end use: for example, a critical clearance, chemical impurities in film, particles on optical components, fibers or particles in a vacuum system, or hydrocarbon deposits on a liquid oxygen service component. Recognition during design of the critical features allows the manufacturing and quality control organization to be made responsible for achieving and maintaining the critical features.

2.4 METHODS OF SPECIFYING CLEANLINESS

In the past the designer has had the tendency to prepare product specifications with such general terms as "must be clean" or "shall be free of all dirt and particles" or "shall be assembled in a clean area." Such specifications are vague generalized statements that can accomplish only a very minimum effort at contamination control. Under such a specification, no one knows what is needed, facilities cannot be well-planned, manufacturing personnel cannot be properly trained, and quality control has no standard to measure the product. This can only result in wasted effort, wasted money, and questionable product reliability.

More recently, it is common for the product specifications to require "build in class XX clean room." This offers little improvement. If there is any possibility of a contamination problem, the natural tendency is for the designer to prescribe the highest class of facility available in order to be on the safe side. This type of specification completely ignores all other factors in a contamination control effort, and does not allow for an optimum manufacturing plan. Further, such a specification does not give quality control a basis for measuring product quality and insuring reliability. A clean room must not be mistaken for a complete contamination control program. For the product designer to specify the clean room requirements leads only to misuse and abuse of clean room facilities, wasted money, effort, and delay. In most instances, the requirement will result only in a superficial contamination control program that will not respond to the real need.

Just as the need for any other tool is identified by the work that is to be accomplished, so is the need for, and the level of, a clean room and other tools for contamination control determined by the features of the product that are critical. The designer's role is to identify the critical features of his design. Only then can preparations be made and steps be taken to achieve and preserve these features.

There are several ways by which the designer can depict the contamination sensitivity or cleanliness requirement of the product. Some of the more readily used techniques are:

a. Identifying the contamination sensitive qualitative characteristics of the product; for example, some typical design notes might be:
   (1) Coated film is subject to deterioration when exposed to relative humidity of less than 50 percent.
   (2) This solution will immediately precipitate if contaminated by ferric material.
   (3) Hydrocarbon residual presents an explosive hazard.
   (4) There shall be no visible tarnish on plated surfaces.
   (5) There shall be no visible evidence of flux residue.

b. Specifying critical tolerances, clearances, finishes, and other features in quantitative terms. For example:
   (1) Maintain clearance of $0.0005 \begin{smallmatrix}+0.00002\\-0.00000\end{smallmatrix}$ at 70° F.
   (2) Maintain 5-micron surface finish.
   (3) Contact resistance not to exceed 1×10^{-4} ohms.
   (4) Alloy shall be 70 to 70.5 percent Fe, 0.005 percent to 0.006 percent Cr, etc.
   (5) Insoluble contaminants not to exceed 200-micron maximum dimension.

c. Specifying proven (accepted) standards of cleanliness. For example:
   (1) LOX clean in accordance with Figure 4-4, AF TO-42C-1-11.
   (2) Contamination level to be according to MSFC Dwg. No. 10419906, Cleanliness Level for Gas Bearing and Slosh Measuring Systems.
   (3) Hydraulic clean in accordance with MSFC-PROC-166B.
   (4) Breathing-gas clean in accordance with AF TO 42B6-1-10.

d. Specifying the cleanliness level of the part or material in terms of particle kind and count, or soluble residual in ppm, based on experience, judgment, and reference. It is important that when the cleanliness level is specified that the method of testing is also specified. For example a typical design note might be as follows:
   The surface of this part prior to enclosure shall meet the following as tested according to ASTM-F24-62T method:
   (1) Maximum of 10 particles per square inch of 50- to 100-micron.
   (2) Maximum of 100 particles per square inch of 5- to 50-micron.
   (3) Maximum hydrocarbon residue not to exceed 7.0 ppm per 100 milliliters solvent per square inch of surface.

e. Specifying proven cleaning processes for a given type or classification of parts:
   (1) Clean in accordance with MSFC Dwg. No. 10411091, Cleaning Bellows and Ducts.
   (2) Clean in accordance with MSFC-PROC-166B, Cleaning Hydraulic Systems.

f. Specify functional test requirements that will include those parameters that would be influenced by contamination; for example:
   (1) Gyro drift rate shall not exceed 0.01 degree in a 36-hour period.
   (2) Bearing torque shall not exceed 2×10^{-3} gms at 2500 rpm after 3 minutes.
   (3) Optical system shall resolve 5-micron objective.

g. Specifying that cleaning processes and cleanliness levels are to be developed to meet final quality and reliability requirements.

Item "g" recognizes that the designer cannot always realistically predetermine the level or degree of sensitivity to contamination. The important idea is that he does recognize a probable degradation of the design from contamination at any point or from any agent during manufacturing, test, shipping, etc. If the designer is faced with a challenge of working toward an indefinite or ideal goal, whereby he cannot predict the influence of contamination even though it is expected to be a factor, the communication

and information loop among design, manufacturing, test, quality control, etc., becomes of paramount importance.

If the designer cannot realistically predict the contamination sensitivity of a part, assembly, or system in practical terms, he must recognize that the development of a contamination control program must proceed as a mutual effort. The design activity should direct that a level of product cleanliness be developed that will meet the end item requirements for reliability or quality and should specify the parameters by which to measure product reliability or quality as affected by contamination. In this instance, the degree of cleanliness as developed should be entered into the product specification upon final approval by the design activity. In such a case the designer, process engineer, contamination specialist, test planner, quality control personnel, and others concerned must work dependently to develop, implement, and refine a program that will deliver the desired quality of product. Only with cooperative effort of all those responsible can an effective program be realized.

2.5 COMMON ABUSES

One of the most common abuses of contamination control technology arises because the designer does not give proper consideration to the contamination sensitivity of the part. For example, it is not unusual to see a drawing and specification requiring that a conventional printed circuit board for a conventional application be fabricated in a clean room. Fabrication in this case includes chemical processing, drilling, machining, plating, and marking. Such a design requirement for fabrication in a clean room is a flagrant violation of good design practice and even common sense. First of all, the clean room in almost every case contributes nothing of value to processes of this nature. If there is a realistic need to maintain a low particle concentration on a printed circuit board, it can normally be achieved by just the final cleaning occurring in a clean room. Fabrication in the clean room prior to precision cleaning will add nothing to the product except cost and delay. Precision cleanliness should not become a requirement during the manufacturing cycle until it actually becomes critical.

The degree of cleanliness prescribed by design must be carefully considered. In all instances, care must be taken so that a higher level of cleanliness than is necessary is not specified. The designer often has the tendency to specify higher levels of cleanliness than required just to be on the safe side. In other cases there is a tendency to specify the highest level of contamination control that is available in a facility. Such a practice may have serious consequences.

Increased costs and serious delay will result if a higher level of cleanliness than is necessary is specified. Unrealistic requirements almost always become obvious in practice and tend to destroy confidence in the general concept resulting in an ineffective unworkable program. Further, attention to realistic contamination control needs during the concept and design will prevent costly engineering changes to facilitate cleaning, testing, or other processes prior to operation.

SECTION 3

NATURE AND ORIGIN OF CONTAMINATION

SECTION 3

NATURE AND ORIGIN OF CONTAMINATION

3.1 GENERAL DEFINITION

For the purpose of this handbook, contamination is defined as any unwanted foreign material referenced against absolute purity. These materials can be ordinary dirt, corrosion products, oxides, industrial dust, spores, fibers, pollen, chemical products, or any organic or inorganic matter which adheres to, comes to rest on, or diffuses into the referenced material, part, or medium. With this definition in mind, it is important to recognize that absolute purity seldom if ever is achieved; there is always some contamination in or on everything and it may or may not be harmful. The important consideration is to control the degree or level of the contamination to a point whereby it will not constitute a hazard or interfere with or degrade the function of the product concerned.

Contamination may be classified in four general categories:

a. Particulate contamination - dust, chips, fibers, etc.
b. Chemical contamination - gases, liquids, water in fuel, CO_2 in O_2, oily films, SO_2 in the atmosphere.
c. Biological contamination - bacteria, virus, fungi, spores, etc.
d. Energy or change of state - light will contaminate film, magnetic fields contaminate iron or nickel, radiation affects living cells and plastics, heat degrades, etc.

Item "d" requires special involved considerations and has implications beyond the scope of any single collection of information; therefore, it is not discussed in this presentation. It is enough that this general category be recognized. The first three items are those of primary concern because they are the most common types of contamination; they often occur together, and the techniques and tools for control are similar. Because of the special nature of biological contamination, Section 10 of this handbook is devoted to the specialized aspects of its control.

3.2 PROBLEMS IN INDUSTRY

What might be a contaminant that requires control in one industry may well be of no consequence in another; but it is essential that unmanageable amounts of foreign matter in the

product be avoided in all industries, since these are likely to produce early failure or serious degradation. Consider some of the common foreign materials found in production hardware.

For example, it is not easy to understand how, but it is not unusual to find failures such as those caused by a 14-inch pipe wrench left in the gear casing of a marine steam turbine, a handful of shop soil in an automatic auto transmission, a 6-inch extension ratchet and deep socket in a rocket fuel tank, a 15-inch spud wrench in a transformer, and a rusty file in a jet engine compressor housing. These problems are present in industry today and, fortunately, in most cases they can be readily corrected in this type product without excessive losses in time and money. On the other hand, these same problems are present in the current generation of miniature aerospace equipment, but they cannot be detected as readily. For example, a metallic particle 450 microns (1 micron equals 1 millionth of a meter, or 0.000039 inch) in diameter can cause a failure in a 0.25-inch outside diameter miniature gyroscope bearing as quickly as a 1/8-inch metal chip in a 2-inch outside diameter lathe bearing.

Contamination in the form of a handful of shop dirt, a rusty file, or gross articles of debris from manufacturing operations is controlled by good shop discipline, good housekeeping, ordinary inspection practices, and most important, adequate motivation and training. Such gross contamination can be and often is a problem, but such contamination is easily recognized and can be prevented without special processes, procedures, or facilities. Control of this type contamination simply reduces to good operating practices.

On the other hand, contamination in the form of particles, or oily films that are practically invisible to the unaided eye presents an entirely different set of problems. This is the kind of contamination that requires special controls, tools, facilities, and disciplines.

Normally, a few particles, or isolated patches of oily film will not cause a problem; however, sometimes a single tiny invisible particle of metal or perhaps a vegetable spore or the oily residue from a fingerprint can cause failure of such items as a high precision photographic device or a miniature electronic component. Usually, it is not the few particles that cause the problem, but the concentration and accumulation of particles, fumes, moisture, etc., that are normally found in industrial environments and the inherent influences of the human factors involved.

The food-processing plants, the pharmaceutical industries, and biological laboratories producing vaccines, antitoxins, and similar products obviously have to maintain stringent controls of foreign materials (see Section 10). In these biological laboratories, effective controls are required to prevent infection of personnel. The advent of atomic energy and the hazards of radiological contamination have resulted in very stringent controls of airborne particles, not only for the protection of personnel working with the materials but also for effective controls to prevent radioactive fallout over the surrounding country side. The control of harmful vapors from many industrial processes and materials for personnel safety reasons is well known and universally practiced (see Appendix - Figure A-2).

3.3 EXTERNAL SOURCES

Many external sources of particulate and chemical matter in the atmosphere are products generated by the industrial community itself. Table 3-1 lists some of the most common external sources of industrial dust, and fumes or gases. These particles and gases tend to move with the wind and thermal currents and in channels created by buildings or natural topography of the terrain. Consequently, they will be airborne into buildings through normal fresh air makeup facilities.

Particle concentrations will vary in different locations and seasons (see Appendix - Figure A-1). For example, in rural areas under normal atmospheric conditions, concentrations up to 40,000 particles per cubic foot are not unusual. In the harvest season these counts will increase considerably. In metropolitan areas counts up to 1,500,000 particles per cubic foot (above 0.5 micron) are not unusual, and research by the USAF has indicated that the general industrial atmosphere has up to 1,000,000 particles above 1.0 micron with normal range and distribution up to 600 microns. Particles much larger can be expected to occur frequently in such a distribution, since such increased sizes and concentrations are a positive function of industrial production processes and operations (see Appendix - Figure A-3).

The specific origin of contamination from external sources is often difficult to determine, but it is of consequence to know the origin in order to eliminate it. The fact that it is dirt and is unwanted in most industrial activities, both from the housekeeping and product quality perspective, is sufficient motivation for industry as a whole to continuously seek methods of controlling the influx of these contaminants into the production and service areas and to control the generation and migration of contaminants

within these areas. However, it is important to keep in mind that aside from personnel health and safety the need for cleanliness relates to the product. The main purpose, of course, is to prevent contamination of the product that may interfere with or degrade its proper function.

Table 3-1

Typical External Sources of Industrial Airborne Contamination

Source	Approximate Particle Size Range - Microns Largest Dimension (1 Micron = 0.000039 Inch)
Combustion Products	
a. Power generating plants	0.5 to 50
b. Refineries	0.5 to 50
c. Commercial transportation (including private automobiles)	0.1 to 10
d. Heating plants (including laundries)	0.1 to 1200
e. Exhaust from chemical processing. (In most cases gases will be harmful as a gas, but corrosion is also caused which creates particulate matter.)	2 to 10
Construction	
a. Erection of new buildings, including grading and earth handling.	1 to 50
b. Demolition of buildings.	1 to 100
c. Municipal construction and repairing (streets, sewers, bridges, etc.)	1 to 100
General	
a. Mining and quarries.	1 to 500
b. Cement plants - foundry and steel mill dust.	0.5 to 1000
c. Coal smoke.	0.01 to 5

In some instances a given contaminant in the environment will not present a problem, but when the contaminant is combined with a second element a potential hazard will exist. Some of the common factors of environment to which materials and hardware are usually exposed are as follows:

a. Dust - Includes all organic and inorganic particulate matter.

b. Temperature - Fluctuations of temperature cause changes in dimensions.

c. Moisture - Includes moisture in the air (relative humidity), which induces corrosion.

d. Vibration and Shock - Includes all environments encountered in processing, handling, and storage.

e. Fumes and Vapors - Induce rapid corrosion of metallic parts and materials, chemical breakdown of many plastic and other non-metallic parts, and accumulate as films on parts.

f. Fungi, Spores, and Bacteria - Induce fungus growth, chemical changes, and corrosion and may present biological hazards (see Section 10).

g. Electrostatic Charge - Caused by handling and movement; causes material to attract and hold contaminants.

All of the above, both separately and combined, have proved troublesome to industry in the past, and much effort and money have been expended to reduce their detrimental effects. Naturally, first consideration was given to the safety and general health of personnel.

3.4 INTERNAL SOURCES

Internal sources of contamination are as important as the external ones, especially since they originate in the vicinity of the product involved. Contaminating matter generated within an industrial production facility occurs through normal manufacturing and service activities. The following is a listing of some of the common sources of internal contamination that can be found in most industrial activities:

a. Machining and Forming Operations

(1) Machining metals, plastics, wood, and wood products.

(2) Drawing, rolling, punching, forming, winding, bonding, grinding, and scraping and sanding metals, plastics, wood, and wood products.

b. Processing

(1) Chemical baths, passivating, etching, cleaning, and painting activities.
(2) Assembling, packaging, moving, and storing.
(3) Welding, burning, and soldering.

c. General

(1) Testing.
(2) Lubricants.
(3) Operating machinery.
(4) Packaging materials, routine paper work.
(5) Maintenance activities.
(6) Conveyors and bailers.
(7) Normal traffic by moving equipment and personnel inside and outside the buildings.
(8) Dust stirred up by janitorial activities.
(9) Particles generated by normal vibration and shock from buildings.

The main problems with internally generated contaminants are caused by their migration by the factory air handling and ventilating systems, personnel and personnel traffic, and production processes and equipment.

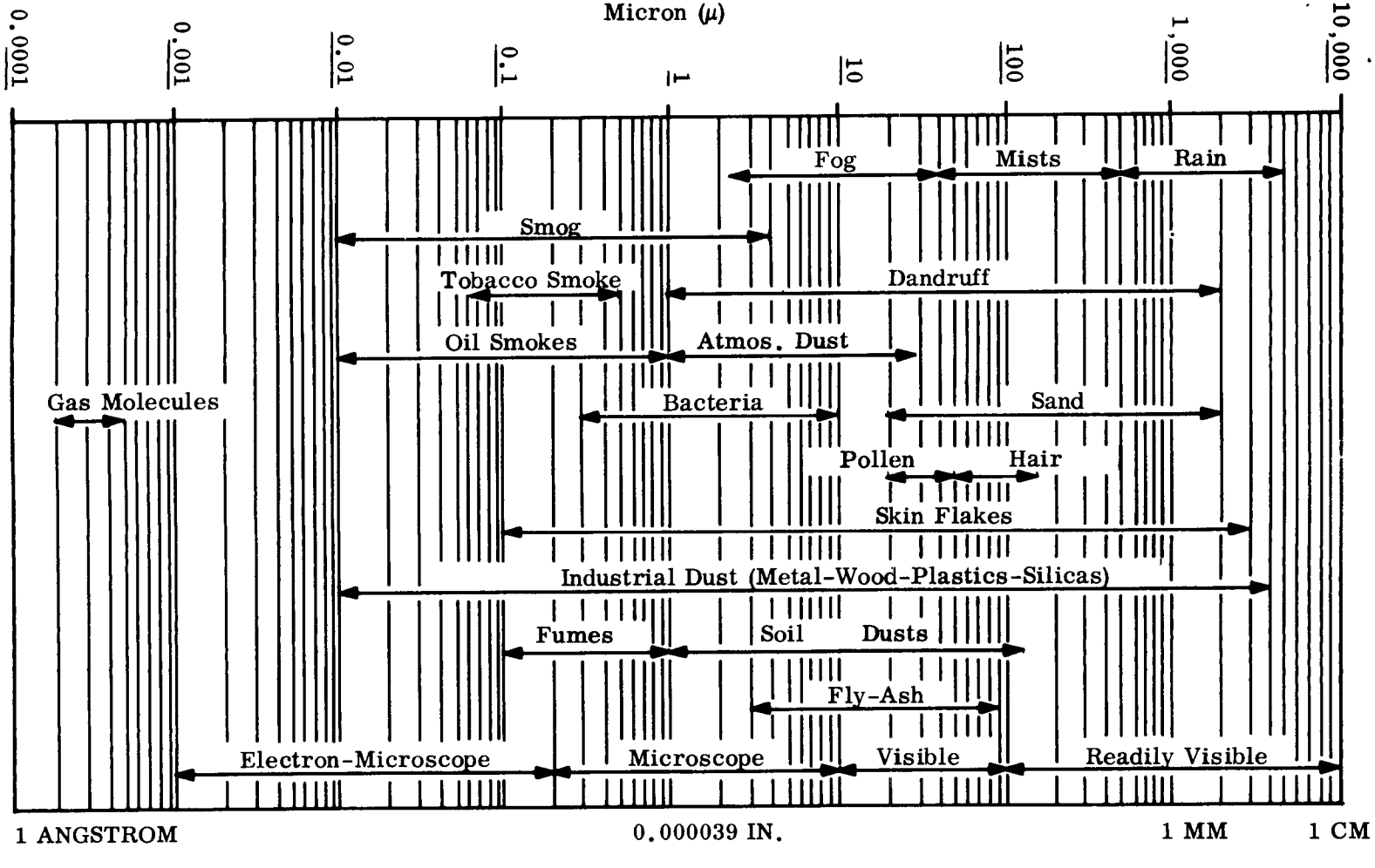
3.5 OTHER FACTORS

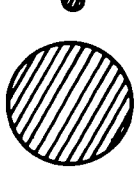
To better understand the nature and influence of the contaminants, further knowledge of their behavior and source is necessary. Consider the following:

a. A human hair is approximately 100 microns in diameter.
b. Tobacco smoke particles average 0.5 micron in diameter.
c. Light dust particles are approximately 5 microns in diameter.
d. Bacteria have a diameter of approximately 1 micron.
e. Fumes consist of particles from 0.1 to 1 micron in diameter.

(A micron, symbol μ, which is the standard unit of measure for particulate matter is 0.000001 of a meter in diameter or 0.000039 of an inch.) Figure 3-1* further illustrates the nature and relative size of various particles. Figure 3-2 illustrates some of the typical shapes of particles. It can be seen that particles will be found anywhere

*NASA, Marshall Space Flight Center, Publication No. R-ME-MPROC-190.0, Operation and Maintenance Procedure, Building 4705, 30 March 1964.





With this figure representing a particle 10μ in diameter, the larger figure represents the cross section of the average human hair 100μ. A major problem in contamination control is the tendency of the small particles to group and form larger particles.

Figure 3-1. Approximate Sizes of Common Particles

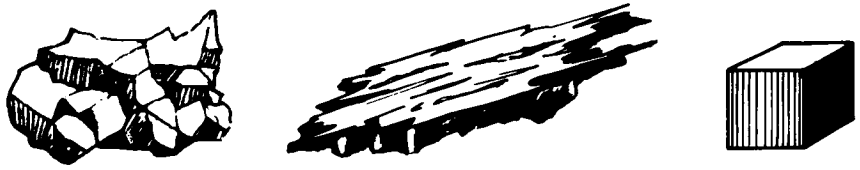
Shape	Appearance	Kind
Spherical		Vapor Pollen Fly Ash
Irregular or Crystalline		Mineral (Sand, Metallic, etc.) Cinder
Flakes		Mineral Epidermis
Fibrous		Lint Plant Fibre Animal Fibre
Floc		Carbon Smoke Fumes

Figure 3-2. Typical Shapes of Common Particulate Matter

there are people. Research has indicated and experience has borne out that to achieve high levels of cleanliness, strict operating limitations must be placed upon personnel. Table 3-2*, taken from a special report of the American Society for Testing and Materials, illustrates the magnitude of influence of personnel.

The activities of operating personnel performing their work will generate particles from the work which have a greater specific gravity and in the larger size ranges than those present in the environment. In addition, these particles will have a considerably higher originating velocity than those produced from the bodies and clothing of the personnel involved. Typical sources of particles resulting from ordinary activities are shown in Table 3-3.

All particles tend to become airborne at the time of origin. Once the originating velocity is exhausted, the particles tend to settle, their rate of settling being dependent upon their mass density, shape, size, and the influence of personnel traffic and air currents throughout the area (see Appendix - Figure A-6).** Since the latter is a dynamic condition, it is not surprising that metallic particles can migrate through a plant air handling or ventilation system, whether mechanical or natural, from a machine shop to a plastic processing area to become embedded in electrical insulation. The same incident can occur from particles settling on an individual and moving from one part of the plant to another, or by any form of contamination adhering to the unfinished product and processing tools and materials as they move from one operation to the next.

It can be seen that particulate matter will result from virtually any movement or activity by people or equipment. A few particles of contaminants in the environment will not, in most instances, present a hazard to the reliability of the product; however, the massive volume normally encountered and the tendency of these particles to adhere to materials, to become re-entrained, to agglomerate and form larger particles because of static charges and other natural forces cause the major problems in the industrial environments.

*See: F. W. Van Huik, Particulate Concentrations in Ultra Clean Rooms, S. T. P. No. 300 American Society for Testing and Materials, 1961.

**Stokes Law is commonly used in computing settling velocities of particulate matter; however, there is a limit to the practical use of these computations because of the wide variety of particle densities and configurations and the vagaries of air currents in an operating facility.

Table 3-2
Effects of Personnel

Personnel Factors	Times Increase Over Ambient Levels for Particles 0.2 to 50 μ
Personnel-Protective Clothing (Synthetic Fibers)	
a. Brushing sleeve of uniform.	1.5 to 3
b. Stomping on floor - no shoe covering.	10 to 50
c. Stomping on floor with shoe covering.	1.5 to 3
d. Removing handkerchief from pocket.	3 to 10
Personnel per se	
a. Normal breath.	None
b. Breath of smoker up to 20 minutes after smoking.	2 to 5
c. Sneezing.	5 to 20
d. Rubbing skin on hands or face.	0 to 2
Personnel Movement	
a. Gathering together 4 to 5 people at one immediate location.	1.5 to 3
b. Normal walking.	1.2 to 2
c. Sitting quietly.	0 to 1.2
d. Dry box or enclosed box with absolute filter - no activity.	None
e. Dry box with hands inside.	0.01

Table 3-3
Typical Sources of Particles

Activity	Approximate Size (Microns)
Crumpling or folding paper.	65
Writing with ball point pen on ordinary paper.	20
Vinyl abraded by a wrench or similar tool.	8
Rubbing or abrading an ordinary painted surface.	90
Rubbing an epoxy painted surface.	40
Handling passivated metals such as fastening materials.	10
Seating screws.	30
Sliding metals surfaces (nonlubricated).	75
Belt drive.	30
Abrading the skin.	4
Soldering (60/40 rosin flux cored solder).	3
Oil smoke particles.	0.1

SECTION 4

NEED FOR AND USE OF CONTROLLED ENVIRONMENTS

SECTION 4

NEED FOR AND USE OF CONTROLLED ENVIRONMENTS

4.1 GENERAL

The concept of utilizing environmental controls to enhance human skills and processes in manufacturing is an inherent part of American industry; it is well established in such fields as the production of pharmaceuticals, textiles, film and chemical components, atomic energy equipment, and certain heavy industries that machine large forgings for gears, turbine casings, and other large precision parts that require close tolerances. In modern industry the environment to which materials are exposed during the manufacturing and test cycles is essentially the atmosphere which contains, in addition to the normal air content, waste in the form of fumes, bacteria, dust particles, pollen, and other airborne debris or contaminating matter, as well as factors of temperature and humidity. Over the years, the effects of these elements upon the industrial products were observed and efforts were initiated to control those that were considered detrimental to product quality.

4.2 NEED FOR CONTROLLED ENVIRONMENTS

Understandably, the earliest controls established were those considered essential to meet an established acceptance quality level (AQL), which, in turn, was based on economic principles. In the last 30 years, varying controls have become common in producing materials, services, and hardware because design, manufacturing, and quality control engineers have developed greater awareness and insight into the influence that environments exert upon product quality and reliability.

For example, manufacturers of large precision gears and shafts for high-speed steam turbines use temperature controls to maintain close tolerances. In producing boiling water reactors, finish cuts on the pressure vessels are performed only at specific times during the day, since the operations occur in a high-bay area in which even with air conditioning, the temperature can be stabilized for these cuts for a maximum of only about two hours a day.

Heavy electrical industries have found it necessary to go to "dry" environments for final assembly of oil-filled apparatus such as power transformers and circuit breakers because if moisture in the air is closed up in the apparatus it will cause early failure

of the equipment. On the other hand, it has been found necessary to maintain high humidity levels in some textile operations to reduce thread breakage.

In other cases, controls were either developed or put into effect by many industries when Federal, state, or local laws required it or when scrap losses or other economic factors indicated a need for improvement*.

Dirt and other foreign matter or contaminants have proved to be the most difficult and elusive elements of the industrial environments to control, and the miniaturized electronics, mechanical, optical, electrical, and hydraulic components used in current generations of defense and space hardware have brought the problem into sharp focus. The lack of access for maintainability, extremely high unit costs, and limited production quantities require elimination of all types of failures, and far too many failures have been attributed to contamination. The present high degree of environmental controls in the aerospace industry has evolved as a result of constant efforts by Government agencies and industry to meet the need to achieve and maintain a high and repeatable level of quality and reliability in products that have increased in precision and complexity.

The state of the art in the design of precision navigation and guidance equipment, as well as propulsion and control devices for aircraft, marine, missile, and spacecraft progressed over the years to the point where its demands exceeded the capability of existing manufacturing facilities and processes. Manufacturing and quality control engineers were continually being confronted with the problems inherent in producing highly complex and reliable hardware with tolerances of 0.000050 inch and with clearances as small as 25 microns in facilities that were designed to produce standard shop tolerances. In addition, many of the materials being used require a stable temperature for various operations because of high coefficients of expansion and meticulous surface finishes. With the ordinary shop atmosphere containing in excess of 5000 particles of dust (5 microns and larger) per cubic foot, such tolerances could not be met. In addition, many of the parts involved were susceptible to rapid corrosion from high humidity while in the unassembled state. The immediate problem was to produce

*The problem of foreign matter in the atmosphere is becoming more acute each year. Recognition of this problem has led to more stringent controls on contamination-producing industries and equipment. In recent years, many metropolitan areas have passed ordinances against air and stream pollution. These have been further advanced by the Federal Clean Air Act of 1963.

an environment compatible with product requirements and to keep the integrity of the design intact until the critical parts were enclosed in their protective envelopes or covers. Objectively, to minimize cost and to optimize control, the facility should provide protection only in the area needed.

Surveys of industries in the medical and pharmaceutical fields indicated that much technology was available, but that this technology required orientation to aerospace hardware. The results were facilities with engineered provisions for controlling dust, humidity, and temperature. These facilities took on two configurations. The first was a "glove box," or unitized work station, where a controlled environment was provided only for the hardware. For small items this was satisfactory, but for large items, large facilities had to be designed and built to hold entire work crews and several major systems. With this "walk in" type facility, the problems associated with personnel, apparel, tooling, etc., became apparent and provisions had to be developed to reduce risks of contamination from these sources. As this type of facility evolved, it was upgraded and dust controls were improved by installing "islands" of more stringent controls within the room in the form of a unitized work station with its own air handling and filtering system. Because of primary emphasis being placed on cleanliness, this type of facility has come to be known as a "clean room". During the past years the industrial clean room as a type of controlled environmental facility (CEF) has played a major role in producing high reliability hardware for all current major weapons systems and space exploration programs. The CEF has become an important tool in American industry*. To describe the CEF as a tool is the only accurate qualification and description which indicates its function.

4.3 CONTROLLED ENVIRONMENTS AS A MANUFACTURING TOOL

The CEF is no substitute for sound manufacturing engineering processes, methods, and procedures. No one would consider doing a job on a turret lathe without first determining the materials involved, speeds and feeds, coolants, and tools. The CEF requires this same philosophy in its operations or the full value of the investment will not be realized. Other considerations beyond the CEF must be taken into account. Personnel, process activities, and ventilation equipment present the most significant

*The American automotive industry has profited from the use of the CEF. In one specific case, Chrysler Corporation found that most failures in its automatic transmissions resulted from minute quantities of dust picked up during assembly. Subsequent construction of a 56,000-square-foot dust-controlled transmission assembly room facilitated a 50,000-mile warranty on their current generation of automatic transmissions.

factors encountered in the production of contamination sensitive items. For these reasons, maximum results from the CEF investment can be expected only if careful analysis is made of the product involved and effective decisions are made in the following areas:

a. Where and when special clean operations should start and stop relative to the manufacturing and test cycle.
b. Whether the need can be more effectively and economically met by subcontracting to an established controlled environment capability.
c. Choice of a complete facility or individual clean work stations; construction details of the facility and air handling equipment; the expansion capabilities and permanency (portable or stationary); and flexibility of the CEF.
d. Classification or degree of cleanliness relative to applicable specifications.
e. Equipment and fixtures.
f. Personnel training, orientation, and apparel.
g. Monitoring the environments.
h. Maintenance.

Failure to recognize every one of these factors has often led to unnecessary expense and frustration in controlled environment operations. It has often been assumed that sound design of the controlled environment would "take care of everything." Unfortunately, this is impractical because of the prominent influence exerted by personnel and processes within the controlled environment. In some instances, the CEF was misused to the extent that many operations that could have been performed under controlled shop conditions were planned and performed in the CEF. In other instances, personnel, spacing, and headcounts were not controlled. Only routine janitorial support was provided; consequently, the facility stayed out of tolerance for extended periods of time and generally created more problems in operating than it solved.

These experiences indicated that such facilities were impractical and that established tolerances were unrealistic. Many times this was true, but on other occasions the problems encountered could be attributed to situations whereby the CEF was not recognized as an instrument or tool in the production process; instead it was considered as an exotic area and used to impress both customers and visitors as a sophisticated production capability.

In considering the use of a controlled environment facility, it is an important point that production levels are considerably decreased because many of the necessary

restrictions placed upon the CEF to control contamination, temperature, and humidity also tend to reduce productivity. The following are the most significant contributing factors:

a. Entry into and from the work area is slowed as a result of donning and removing special apparel, use of air showers, and use of other equipment such as shoe cleaners and washing facilities.
b. Because of necessary restrictions on eating and drinking in the facility, break periods are longer than usually allocated in normal shop areas.
c. Material does not move in and out freely as it does in the ordinary shop, since specific requirements are usually needed to prevent contaminated material from entering the facility.
d. Work often must be routed in and out of the facility for subsequent operations.
e. Cleanliness of the product usually has to be verified.
f. Special protective covering for the work is usually required and special tools, fixtures, and equipment designed for clean operation are not always the most efficient.
g. Operating procedures are difficult to develop and often must be determined by trial approach resulting in frequent changes to achieve optimum results.
h. Documentation often becomes a heavy burden without a real need. (Some documentation is justified, of course, but there is a tendency for it to get out of hand.)
i. Unscheduled shutdowns can often occur from out of tolerance conditions.

The preceding restrictions can be foreseen, and provisions can be made to offset time losses resulting from these restrictions. On the other hand, the facility will be a contributing factor in cost savings by reducing rework and lost time caused by contamination.

After it has been established that a controlled environment facility is a necessary element in a contamination control program, many factors are to be considered relative to designing, building, and operation, of which the following can be considered the most significant:

a. Probable nature and sources of contamination related to the sensitivity of the product.
b. Size of the product and the handling criteria (the cleanliness objectives may often be met by use of individual unitized work stations).
c. Design and construction of the facility.
d. Filters and filter media supplying air to the facility.

e. Development of specifications, standards, and procedures for contamination sensitive operations.

f. Equipment and fixtures.

g. Personnel instruction and training, including supervisory and staff personnel.

h. Apparel, including laundry.

i. Monitoring the controlled environments.

j. Maintenance.

The preceding subjects will be discussed in detail in the following sections.

SECTION 5

CONTROLLED ENVIRONMENT FACILITY DESIGN AND CONSTRUCTION

SECTION 5

CONTROLLED ENVIRONMENT FACILITY DESIGN AND CONSTRUCTION

5.1 GENERAL

Controlled environments have evolved from an early approach of upgrading the existing factory facilities to the present concept of specially designed, closely controlled, and accurately operated facilities. In many cases the upgraded or segregated section of a shop that is used as a clean facility is quite adequate for some work, depending upon the level of cleanliness to be achieved. However, as tolerances, precision, and contamination sensitivity of a product become more demanding, it is necessary to equip a facility with an appropriate controlled environment that will assure quality and reliability. In other words, it is necessary to provide the proper tools.

The clean room must be thought of as a special kind of controlled environment facility that is used as a tool to do a specific job. The designers of the clean room must consider the manufacturing, test, shipping, storage, etc., cycle of the product in order to determine where and to what degree a controlled environment is needed.

The design of the clean room becomes an important economic consideration. If the design is not adequate, costs will rise rapidly in scrap and rework. In addition, the more area involved and the higher the levels of control required cause the facility construction and operating expense to mount rapidly. Further, if there is an over-design it soon becomes apparent to the operators and tends to destroy confidence in the whole program which in turn breeds carelessness and poor practice. The designer of the clean room must carefully weigh all factors in order to evolve the most economical, and effective clean operation.

5.2 LAMINAR FLOW VERSUS CONVENTIONAL FLOW CLEAN ROOMS

Two design concepts for industrial clean rooms are in use. The older type is referred to as conventional flow. This type utilizes standard packaged air handling and distribution systems.

A more recent innovation utilizes a laminar flow principle whereby one wall of the facility is made up of a bank of high-efficiency filters and the opposite wall is used as an exhaust grill. Theoretically, the air, after being forced through the filters at a velocity of 90 to 100 fpm (about one mile per hour) will move directly to the exhaust grill in a straight line flow. This design is also available as standard packaged components or modular elements. Tests with smoke and various types of dust show that this design has a very rapid recovery rate from a contaminated condition. The clean air stream makes only one pass through the area. This factor tends to reduce the problems of deposition and resuspension of dust and other light particulate matter.

Because of the success of the laminar flow design in many installations it has recently been given a great deal of publicity and emphasis. However, it must be pointed out that an operating clean room is occupied. Furniture, equipment, personnel, and any movement in the room will interfere with the laminar flow principle. In fact laminar flow is not achieved. However, the advantage that is accomplished in such an operating facility is that a large mass of moving air tends to entrain and sweep downstream particles of contamination as they are generated and made airborne. Of course, this is desirable when high levels of cleanliness must be achieved.

Unfortunately, the theorists have been promoting the laminar flow concept as a clean room design, exclusive of all other considerations. The principle is a good and useful one; however, it does not meet all needs and is not justified in all cases. The clean room can only be justified as a tool to serve a practical need.

The essence of the problem is that many proponents of the laminar flow design classify all clean rooms as either laminar flow or non-laminar flow. An immediate controversy arises as to which design is best. This controversy is meaningless because any facility regardless of design may be considered best for a particular need, if the design has proven to be successful in meeting the cleanliness objectives. Many installations of various designs are operating successfully every day. The essential requirement is that the clean room must be adequate to meet the needs of the product.

In fact, the classification of laminar flow or non-laminar flow (conventional flow) is erroneous and misleading. The distinction should not be made. A well-planned, well-designed, effective clean room may employ features from both concepts. In theory, the laminar flow design in its pure form may achieve the greatest degree of cleanliness, but it is less flexible, more restrictive to the operation, more expensive, requires more maintenance, and is more limited in size than the conventional flow design.

On the other hand, the so called conventional flow does not achieve as high a cleanliness level, does not recover from a contaminated condition as fast, and requires more janitorial support.

In practice, good design will trade-off the advantages and disadvantages of each to approach the optimum design for a particular need. Figures 5-1 and 5-2 show the theoretical, unoccupied rooms that conform to the purely laminar cross flow and the conventional flow. The major advantages and disadvantages of each are listed in the following pages to show the relative merits of each theoretical design.

5.3 COMPARATIVE ADVANTAGES

The advantages and disadvantages of the laminar cross flow design are the following:

a. Advantages
   (1) Minimizes problems of deposition and resuspension of particles.
   (2) With suitable storage areas for in-process materials, this type of facility can often be secured for weekends or holidays, if provisions are made for an early startup (one hour prior to start of the work shift).
   (3) Will generate a greater number of air changes per hour.
   (4) Rapid recovery from a contaminated condition.

b. Disadvantages
   (1) Greater opportunity for failure (rupture of seal) of a single filter module which will require shutting down the room and recleaning and/or rework.
   (2) Uniform velocities are difficult, if not impossible, to attain, resulting in eddy currents and turbulence that significantly reduce the desired laminar flow qualities of the facility. Personnel, furniture, equipment, and movement further interfere with the uniform airflow and reduce the benefit of this feature.
   (3) Efficient work flow is sometimes difficult to achieve in order to gain the benefits of the fixed air flow. (Down stream work is subject to upstream activity.)
   (4) Less flexible in size with limited expansion capabilities.
   (5) Cost per square foot is usually higher than conventional flow.

The advantages and disadvantages of the conventional flow design are the following:

a. Advantages
   (1) Material flow is less critical and, therefore, simple to lay out.
   (2) Design tends to be more flexible allowing several areas to operate off the same air handling system.

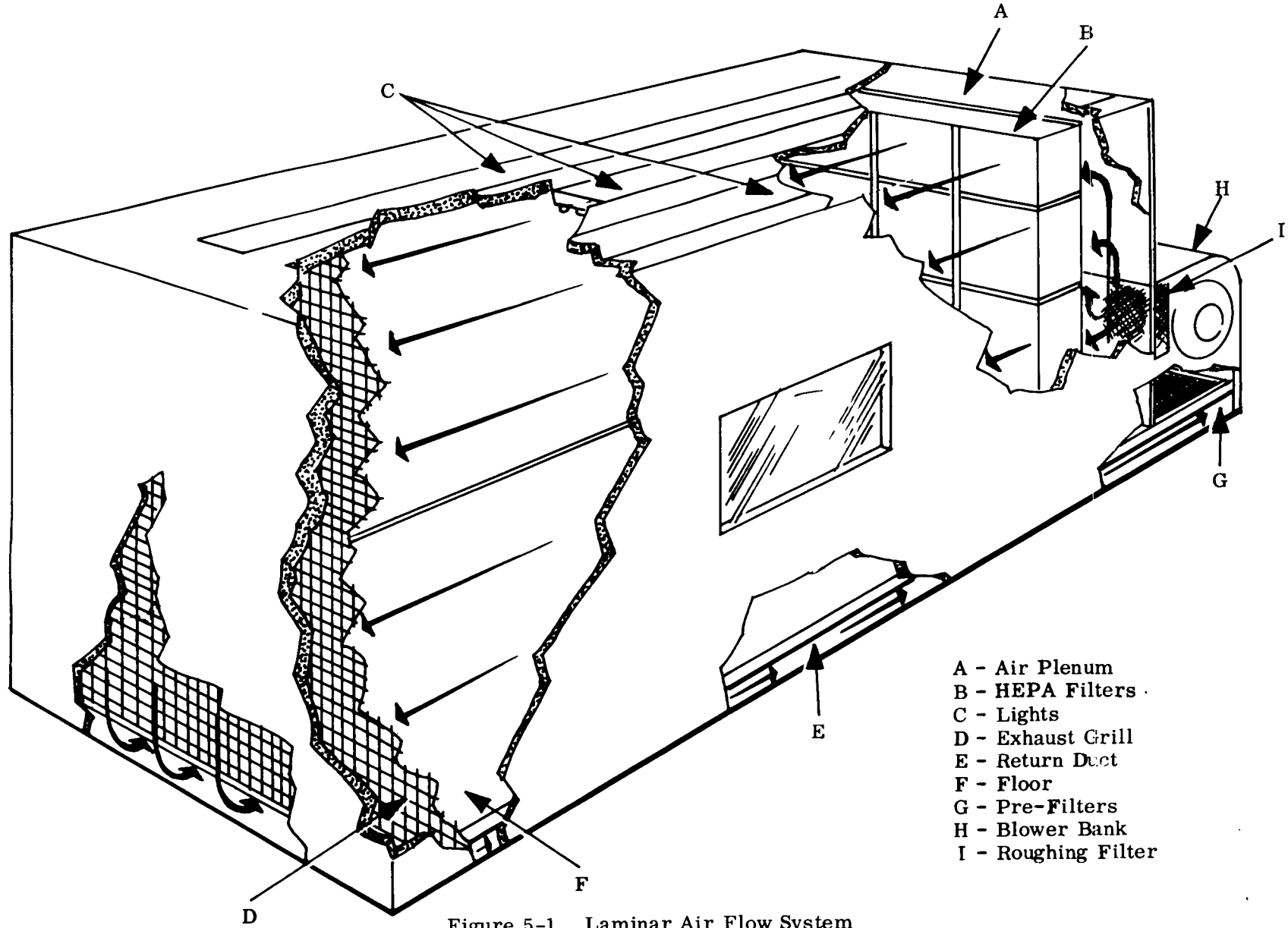


Figure 5-1. Laminar Air Flow System

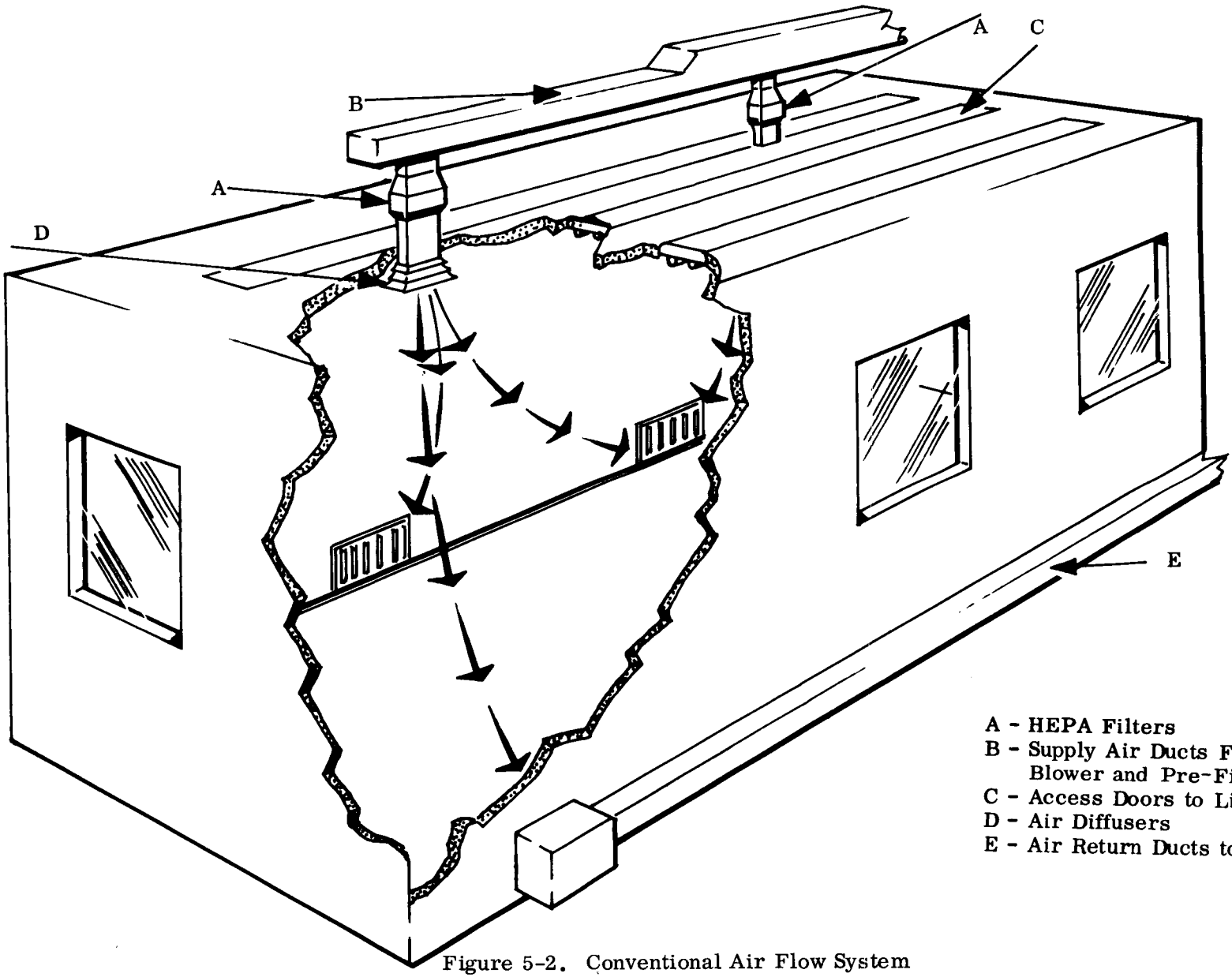


Figure 5-2. Conventional Air Flow System

(3) Filters and air handling system are less complex and easier to maintain, minimizing down time for maintenance and routine final filter changes.

(4) More flexible in size and easier to expand.

(5) Less expensive than the laminar flow types (construction and operation).

b. Disadvantages

(1) Slower recovery rate from a contaminated condition (purge).

(2) Personnel capacity usually will be less.

(3) Fewer air changes, normally 20 to 25 changes per hour.

(4) More janitorial service required.

When considering the advantages of a single pass of air moving horizontally through a room, a limiting factor is that this does not assure the removal of particulates greater than 10 microns. These particulates will tend to fall out. In addition, the originating velocity of particles generated during an operation is not affected by the air stream. The air stream moves at approximately 1 mph, and particles released by mechanical operations (such as tightening screws) will be moving at up to 25 mph, and in most cases, will not be in the main air stream. Once particles have fallen out or have become attached to the surface of an object, the moving air will not remove them.

Additional advantages may be achieved from the laminar flow concept by the use of a vertical flow principle. Vertical flow facilities are constructed so that the entire ceiling comprises the filter bank and the supporting floor is the exhaust grill. Such a facility takes advantage of gravity as well as the moving air stream to remove particulate matter. Consequently, larger particles are removed and greater efficiencies achieved. Such a facility will accommodate a greater number of people and efficient work flow is readily achieved. The disadvantages of vertical laminar flow are the obvious construction difficulties, the size limitation imposed because the entire ceiling is the filter bank, and the lack of flexibility. There are further operating difficulties caused by the working floor grill construction which allows small parts to drop through. In general, because of very high cost of construction and operation it is only in unusual situations requiring extremely high cleanliness levels that the vertical laminar flow will prove practical for a full size clean room. Figure 5-3 illustrates the construction features of a vertical laminar flow design.

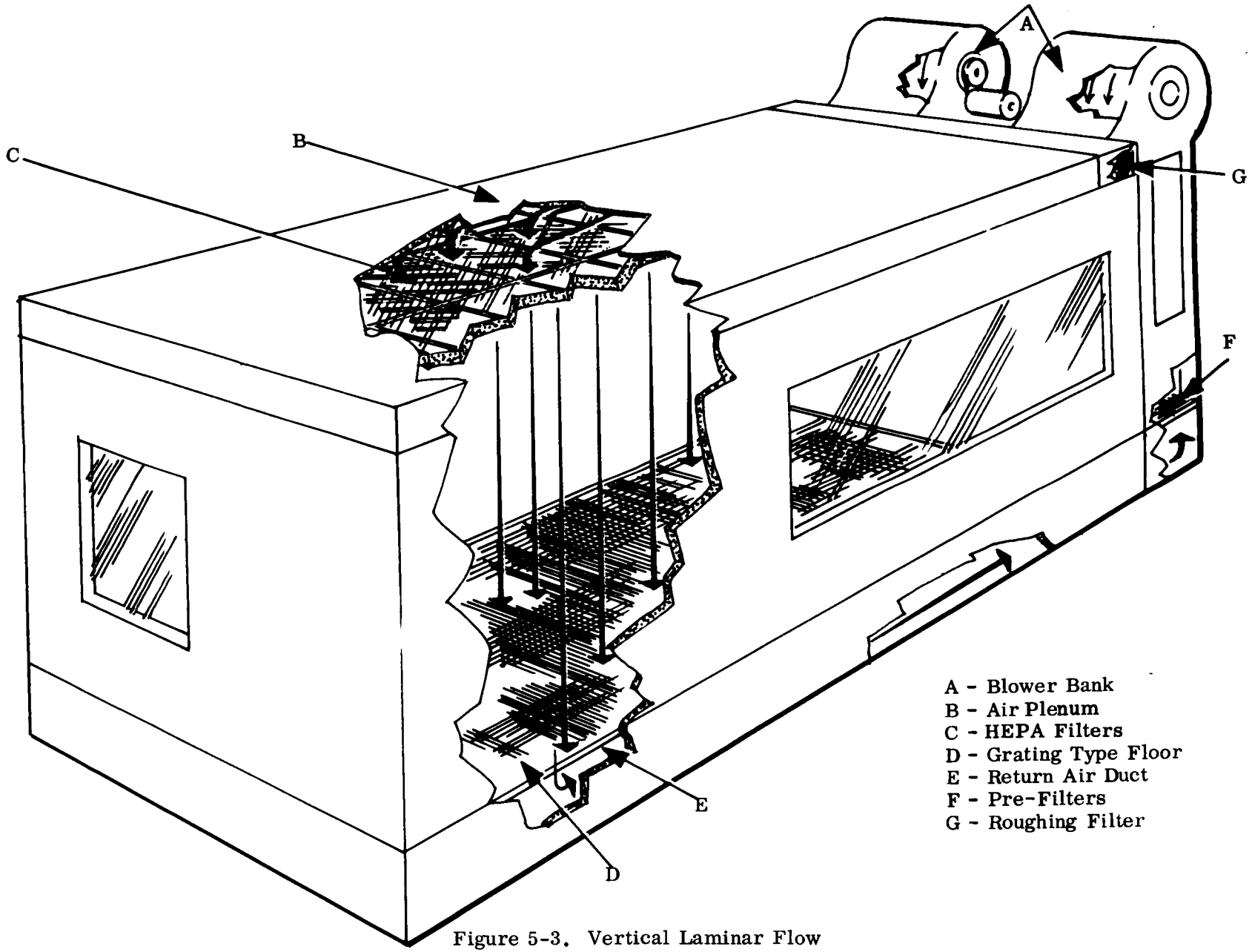


Figure 5-3. Vertical Laminar Flow

In a conventional flow room the air inlets and returns should be carefully designed and located to minimize dead air spots, turbulence, and eddy currents. By carefully choosing the location and number of air diffusers and exhausts, the concept of a mass of air moving through the facility in a single pass can be approached with resulting advantages. In other words, the concept of the moving mass of air changed in a single pass can be approached by the conventional design. It would not be accurate to classify the result as either the conventional or laminar flow design; instead, it may be thought of as a combination vertical laminar flow and a conventional flow facility. Figure 5-4 illustrates such a clean room design that has been widely and successfully employed. This design may prove to be the optimum design for most applications.

5.4 DESIGN TO FACILITATE MAINTENANCE

Careful study of the equipment and materials available for the industrial clean room will facilitate decisions that will aid in the economical and effective maintenance of the clean room at the desired operating levels. These decisions will be influenced by the kind of clean room being considered, by the type of installation, and whether it is portable or permanent. Properly, the maintenance factor should have a great influence on the design.

The following are typical considerations of maintenance that the designer of the facility should take into account:

a. Locate machines (pumps, motors, blowers, etc.) outside the room.
b. Provide service corridors around the facility with access to service process equipment.
c. Exhaust cooling air and air from pneumatic devices.
d. Noncorrosive, nonsloughing materials in air handling system.
e. Nonsloughing, nonabrading materials for floors, walls, and ceiling that are readily cleaned. (Rounded corners reduce dust traps.)
f. Easily cleaned and maintained lighting system.
g. Close attention to door hinges and hardware because of heavy duty service against positive pressure.
h. Interlocks (mechanical or electrical) on air locks or pass-through windows.
i. Locate instrumentation outside the room when possible.
j. Maintainability of power and service utilities without requiring entrance to the area.
k. Communication devices to minimize the need for personnel entry.

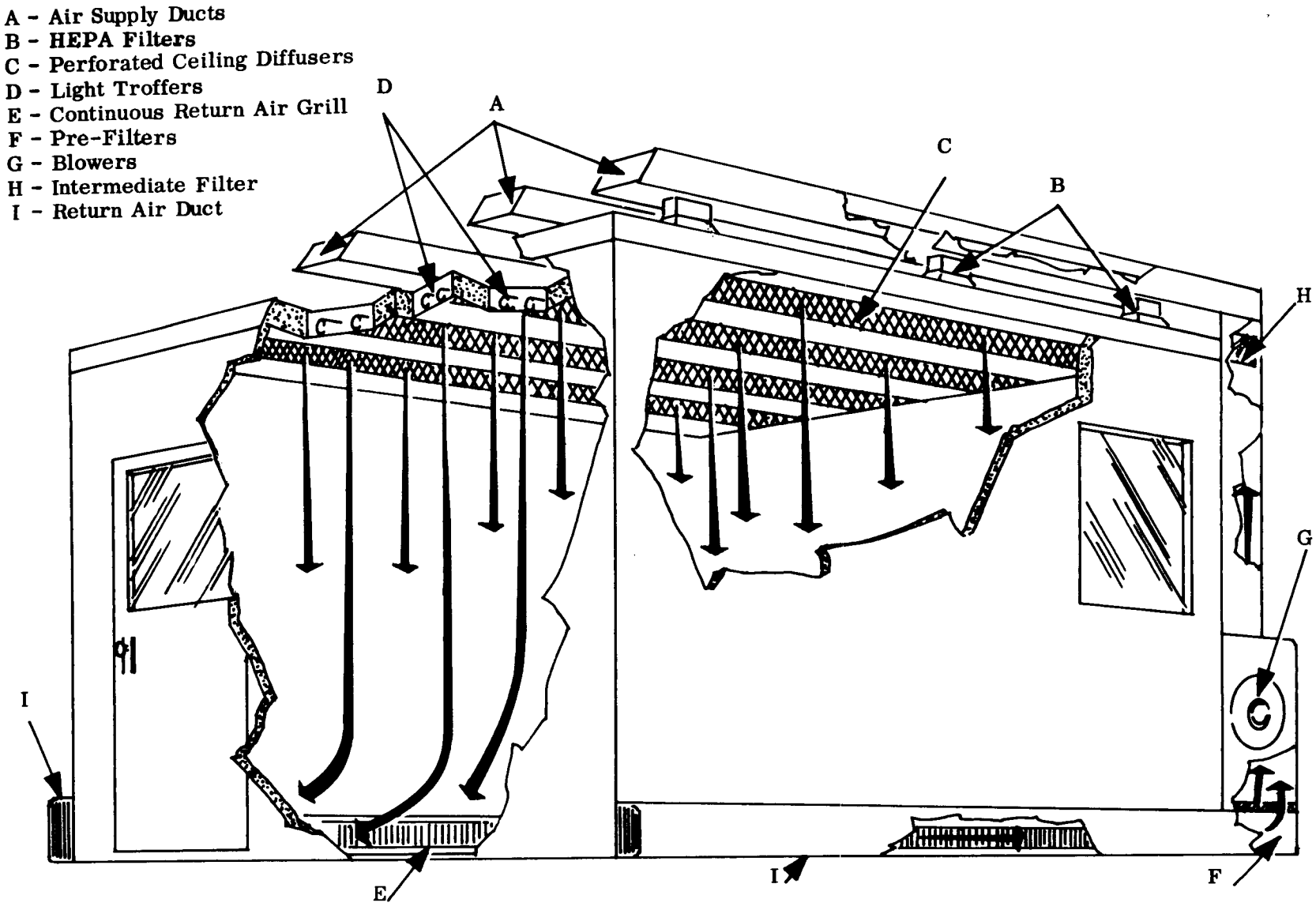


Figure 5-4. Conventional Flow Facility Modified to Utilize Advantages of the Modified Laminar Flow Concept

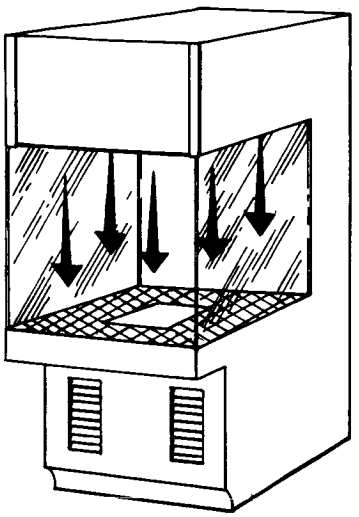
5.5 UNITIZED WORK STATIONS

It must be remembered that miniaturization and close tolerances initially led to the need for clean rooms. Because of inherent precision and small size, the majority of work requiring very clean atmosphere can be performed at a single work station. The need for high orders of clean environments can usually be met by environmental control of an individual work station.

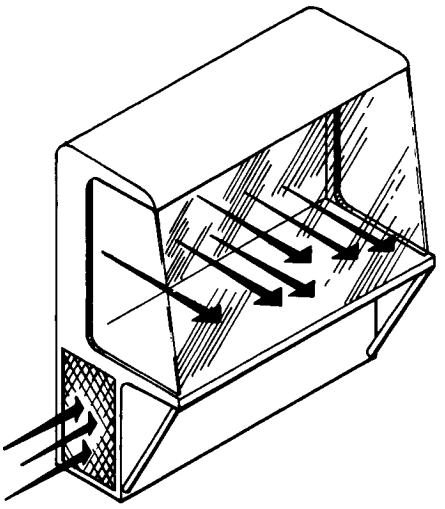
Unitized work stations (Figure 5-5) are used extensively in clean operations. They were developed originally from the dry boxes and similar biological control cabinets used in the medical and biological research fields. The general industrial unitized work station uses a pre-filter and a high-efficiency filter to remove contaminants from the air. They also operate at a positive pressure and are utilized for the more critical contamination sensitive articles processed in the clean room. In this application the stations also tend to enhance the level of cleanliness within the clean room, since they are constantly recirculating the air within the room through their high-efficiency filters which will entrap many airborne particulates. These stations have also proved useful for inspection stations at receiving inspection and in open shop areas where precleaned or contamination sensitive materials must be opened for inspection or adjustment. These work stations can be used singly or in series.

Both conventional and laminar flow work stations are in general use. Some units include air conditioning systems to maintain stable temperatures and humidity levels. Others provide inert atmospheres ("wet" or "dry") as required. In addition, individual stations with reversed blowers and exhaust ducts may be required for operations inside the clean room such as grinding, soldering, etc., that might otherwise contaminate the entire area.

The design selected for the basic clean room should by necessity be oriented toward the product or service to be performed in the area, but consideration must be given to the useability or removal of the facility once the original need has been satisfied. The need for the cleanest areas normally will not require anything larger than a single unitized work station or a series of such stations within the clean room. The simplest form of the conventional flow clean room with unitized work stations (perhaps laminar flow stations) will usually be of greatest value for the majority of applications.



Unitized Work Station—Vertical Flow



Unitized Work Station—Horizontal Flow

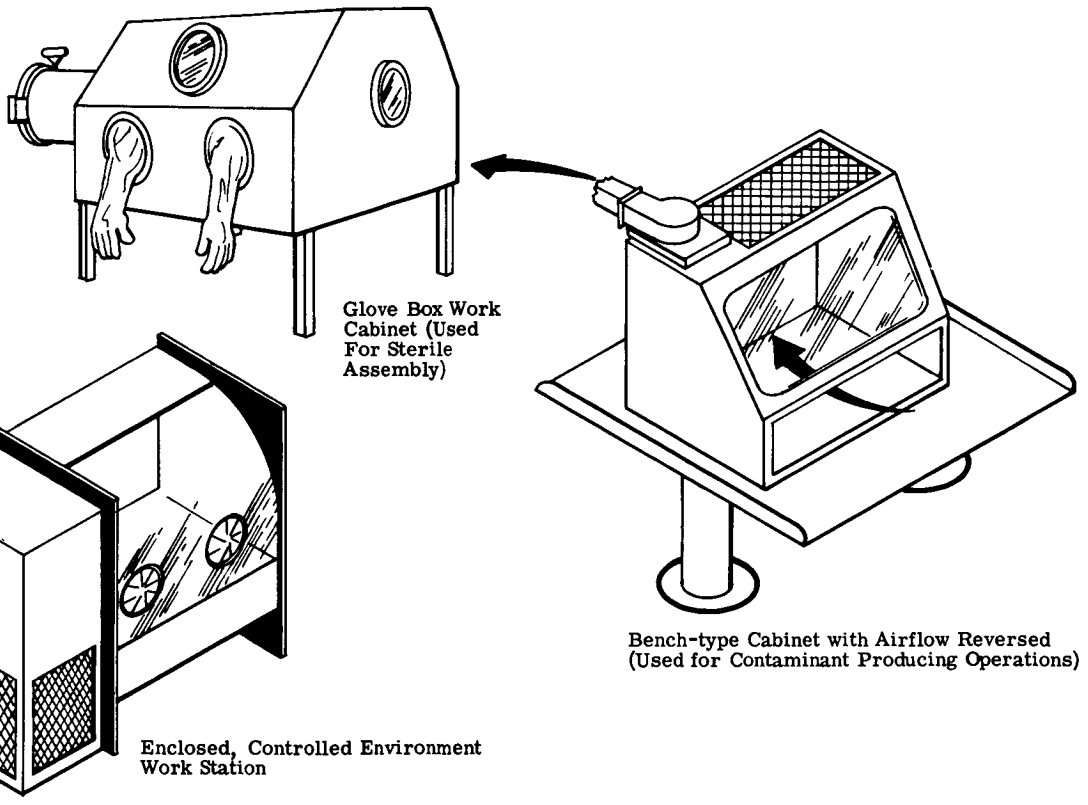


Figure 5-5. Typical Unitized Work Stations

5.6 AIR HANDLING, FILTERS, FILTER MEDIA

The industrial atmosphere contains many elements, some of which can cause significant degradation of machinery, equipment, production hardware, and materials. With the development of industrial clean rooms, three-stage filtering systems were introduced to effectively control these elements. In this system an initial or first filtering stage (called the roughing filter) with an inexpensive felt, cloth, or fiberglass media is used to filter out massive concentrations of contaminants, especially in the larger size ranges (above 10 microns). The second stage is usually a fiberglass or electrostatic electronic filter with efficiency ratings from 35 to 85 percent (35 to 85 percent of all particles above 0.3 micron)*. These first two stages of filtration are normally found on the input side of the fan and operate at a static pressure equivalent to less than 0.7 inch water gage. The final stage filters have the highest efficiency (99.97 percent of all particles above 0.3 microns) and are normally located just before the diffuser or air inlet**. These filters operate initially with a static pressure equivalent to about 1 inch water gage, and this head will build up over the life of the filter to about 2 inches water gage pressure drop across the filter when these filters are used at their maximum rate of flow capability.

A fourth filtering stage is sometimes utilized to remove hydrocarbons. This is important in facilities that process equipment or components such as liquid oxygen lines, valves, etc., that must be free of hydrocarbons. These filters are usually activated charcoal and are located just after the second-stage filters***. Figure 5-6 shows a typical layout for a conventional flow clean room, including the optional charcoal filters.

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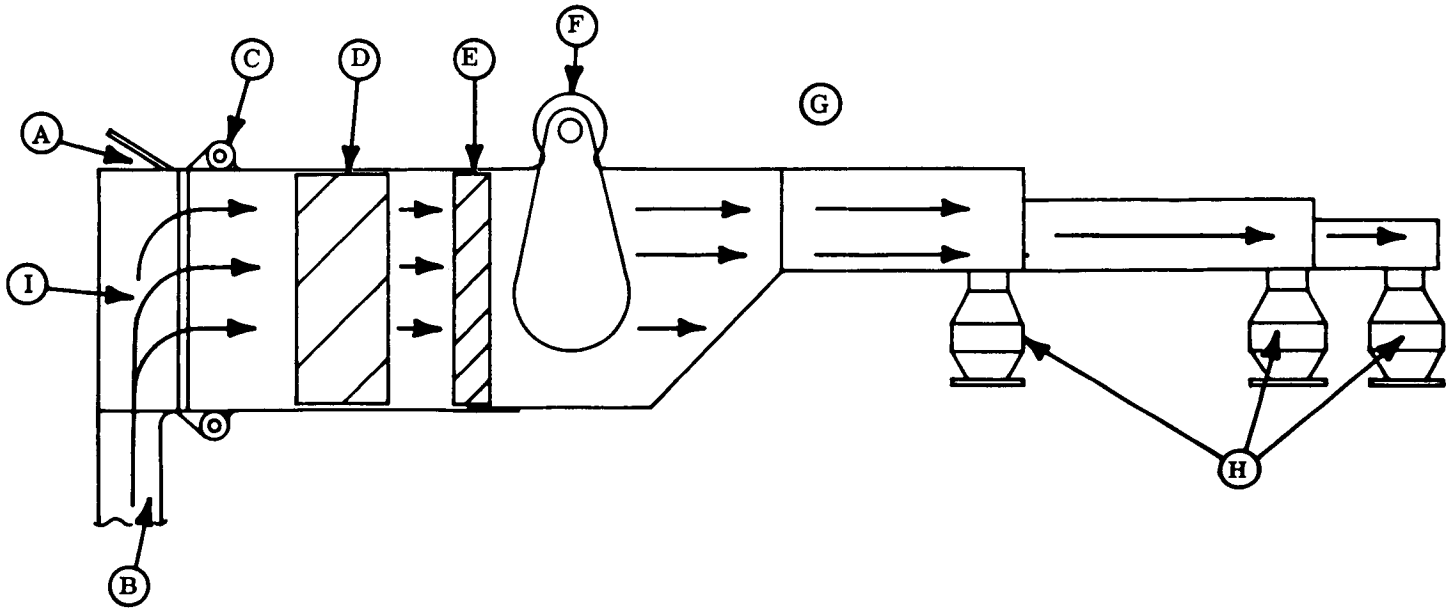
* Efficiency ratings are in accordance with MIL-STD-282, using the DOP (dioctyl phthalate, a chemical smoke) tests developed by the Army Chemical Warfare Department.

** These filters, commonly called high effeciency particulate air (HEPA) filters, were developed by the Atomic Energy Commission to effectively filter large volumes of air at reasonable cost. This design is based on early work by the Army Chemical Warfare Department. These filters are commercially available and are capable of operating at temperatures in excess of 1800° F.

***The activated charcoal filter is used extensively for fume and odor control in hospitals, restaurants, and other public places. Air Engineering Magazine reports that these filters will absorb up to 50 percent of their own weight in such contaminants and one cubic foot of charcoal has 2, 000, 000 square feet of absorbent surface.



A - Make-Up Air Inlet
B - Cold Air Returns
C - Roughing Filters (Throwaway Type)
D - Intermediate Filters
E - Activated Charcoal Filters (Optional)
F - Air Moving Equipment
G - Main Air Trunk
H - Final Stage (HEPA) Filters
I - Air Flow

Figure 5-6. Typical Layout for a Conventional - Flow Clean Room

The air handling system is usually "over-designed" to the extent that dirt buildup in the HEPA filters can be compensated for. Special care is required to insure effective sealing around the pre-filters after each installation or change. This prevents early loading (clogging) of the HEPA filters, thereby assuring their full useful life. In addition, the frame around the HEPA filters must be carefully sealed to insure that only final filtered air is introduced into the clean room. Usually all duct work located after the final filters is stainless steel, polyvinyl chloride(PVC), or similar low-particle shedding materials that are resistant to corrosion and flaking.

Positive pressures are established and maintained through a series of dampers or shutters located in both the supply and return ducts. Conditions of pressure, temperature, and relative humidity are generally recorded and/or indicated at a centrally located instrument panel outside the area. The air ducts are equipped with probes or other connections to allow checking of the air at any point in the system. Probes are also located on each side of the final filters for checking the pressure drop across the filters with manometers. In some instances manometers are installed permanently to facilitate such readings.

As much of the return air as possible is reclaimed, since it is relatively clean and near the desired temperature and humidity when compared with ordinary shop air, but usually about 25 percent fresh air makeup is required. This air is introduced into the system at the first filter stage and is normally controlled through an automatic damper arrangement. Other components to regulate temperature and humidity such as heaters, reheaters, primary cooling coils, secondary cooling coils, and humidifiers, are usually centrally located in the main air plenum, but can be decentralized if required.

5.7 FURNITURE, EQUIPMENT, AND TOOLS

Furniture and equipment for the industrial clean room should be selected with the objective of minimizing maintenance and cleaning in order to reduce physical activity within the clean room. Good-quality industrial type trucks and cabinets will serve quite well for most applications, and items such as chairs, work benches, and similar equipment designed and manufactured for clean room use are available from many sources at reasonable cost. When possible, specially constructed equipment should be avoided and standard equipment used; however, it must be remembered that the requirements for furniture and equipment will vary with the product requirements.

The following are general design criteria that should be considered in selecting clean room equipment:

a. Furniture

Furniture should have a minimum of sharp edges and cracks; where possible, rounded corners should be used. Ledges and horizontal cracks should be avoided. Finishes should have a tough, nonflaking, nonchalking, abrasive-resistant surface such as that obtained with epoxy or urethane paints. Work surfaces should be of laminated plastic resistant to heat, moisture, abrasion, and flaking. Stainless steel can also be used, but surfaces should be treated to minimize glare. The clean room should be provided with the capability of operating for extended periods without maintenance. The design should be simple to allow minimum areas for the entrapment of contaminant material. All moving parts (gears, sliding mechanisms, etc.) in adjustable tables, chairs, stools, etc., should be enclosed or covered.

b. Tools

Tools should be selected to minimize particulate matter generated by their use. The following criteria will serve to minimize this problem.

(1) Good quality chrome-plated hand tools should be used.

(2) Where large rough castings such as vises, clamps, and similar items are required, the rough surfaces can be filled, smoothed, and finished with an epoxy or urethane paint.

(3) Pneumatic and vacuum connections should be of stainless steel and quick-disconnect in design. Factory air should not be released in the clean room. Hoses should be of polyvinyl or Teflon to minimize particle generation from abrasion.

(4) Glazing and sealing materials should be of polyvinyl, silicones, epoxy, or polyurethane materials to insure durability, long life, and minimum particle generation.

(5) Special equipment, such as test racks and consoles, should be finished with abrasive-resistant finishes and, where possible, moving parts should be shrouded with a vinyl boot or other suitable device to contain excessive contamination. Irregular shapes and cavities should be shrouded or filled. Cabinets, consoles, and similar equipment should be enclosed with removable access panels to facilitate maintenance.

(6) Crinkle and similar decorative type finishes should be avoided when possible.

c. Special Devices

(1) Friction points other than power driven ones should be equipped with Teflon, nylon, or other self-lubricating bearings.

(2) Stainless steel ball bearing hinges or an equivalent should be used for doors and openings. Use of continuous (piano) hinges should be avoided.

(3) Where casters are required on portable equipment, sealed bearing wheels with a vinyl or rubber bumper guard around each caster should be used. The casters should be equipped with vinyl tires and sealed ball bearing swivels. When shock mounting of the equipment is desirable, a low-pressure butyl tire is acceptable where effective mounting cannot be accomplished on the chassis.

(4) Stainless steel cables or nylon covered wire rope should be used where lifting devices are required.

(5) Passivated stainless steel tubing, anodized aluminum, or equivalent non-corrosive material should be used for structural members of special equipment.

(6) Welds on fixtures, etc., should be continuous, ground, and polished.

(7) All sharp edges and square corners should be rounded.

(8) Where equipment rests on the floor, the contact surface should have a large cross-sectional area to minimize damage to the floor.

5.8 SPECIAL FEATURES

The design of the clean room must include provisions for service and personal use. Entrance vestibules, air showers (filtered air only), shoe cleaners, tacky mats, and other similar devices are normally needed. In addition, there is usually a requirement for change areas, eating areas, rest rooms, etc. These functions can often be served by existing facilities requiring only a plan for their controlled and effective use. Careful planning of the location of the clean facility within the existing plant will usually provide access to some personal areas. When this is not practicable, the clean room will require the added ancillary features and provisions for control.

Additional clean room design features which have proved useful in controlling cleanliness are as follows:

a. Communication systems—telephone, intercom, talk-through boxes, etc.

b. Windows—allow visitors to observe operations without entering the clean room. (Windows can be used too extensively with the result that clean room personnel feel they are on display).

c. Use of pastel colors for walls to reduce glare.

d. Central vacuum system—eliminates the need for taking a vacuum cleaner into the clean room.

e. Coved corners eliminate potential dust traps.

f. Pass through—door type or air curtain.

5.9 LIGHTING

An area of importance in clean room design is the illumination level in various portions of the controlled area. NASA facilities generally are guided by the provisions of NASA facility publication NPC 321-1, April 1965, entitled Design Criteria and Construction Standards.

For laboratories, a minimum of 100 foot-candles at the desk top is recommended for close work and 500 foot-candles minimum for fine work. These are also the recommendations of the Illumination Engineering Society. A problem arises when the word minimum is used. A level of 400 to 500 foot-candles throughout an installation certainly meets the specification but results in eye fatigue, harshness, glare, reflection, and other undesirable qualities. Personnel may object to working in the room without really knowing the reason why. The heat generated by high levels of lighting cause additional problems.

SECTION 6

OPERATION OF THE CONTROLLED ENVIRONMENT FACILITY

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6.1 GENERAL

The basic purpose of the controlled environment facility is to prevent the entry of contaminants into the controlled atmosphere and to control conditions within the confined area to achieve a specific ambient atmosphere for the work. All factors that may influence the controlled environment must be taken into account.

Primarily, the proper design and construction of the facility prevents external airborne contamination from entering the controlled atmosphere. However, external contaminants can also be brought into the room by materials, tools, and personnel. The best, most elaborate efforts of clean room design and construction are quickly defeated if the entry of personnel and materials is not controlled.

One of the first considerations in the operation of a clean room is to prevent the entry of all but those materials essential to the process. This places restriction on the operation because it does not usually permit the most efficient processing. However, if the clean room operation is to be secure, such restrictions are necessary. It is also necessary to provide a means to clean materials or parts before they enter the clean room to prevent entry of contaminants. This cleaning is not a final precision cleaning but is intended to remove surface dirt, corrosion, or other gross contaminants that would be undesirable in the clean room.

Personnel are usually the greatest single source of contaminants in a clean room. Not only are contaminants brought in on the personnel but normal human functions continue to generate contaminants. An ideal means of preventing contaminants from entering an area, is to prevent people from entering. Of course, this is not practical, but it is with this as an ultimate goal that personnel entry into the facility is controlled. In many cases, there is little danger to the product from adverse effects of personnel contamination; however, when there is such a danger, the proper degree of precaution must be taken and appropriate personnel disciplines must be enforced.

The clean room is intended to provide a particular environment for a particular operation. If operations that do not require a clean environment are placed in the clean room, the environment will be degraded unnecessarily. Although the separation of cleanliness sensitive operations from other operations does not usually permit the most advantageous work flow, it is a primary consideration and it is important to evaluate the optimum compromise. As a general rule, it is desirable to place only contamination sensitive articles or processes in a clean room, and then only for the period, or during the process, when the article is contamination sensitive.

6.2 OPERATING PROCEDURES

The design of the controlled environment facility is a major factor in determining its operation and control. For each facility, a procedure must be developed for its continuous successful operation. The procedure should take the form of a written document that implements provisions for control of processes and personnel in order to achieve and maintain the desired environmental conditions. While preparing the written procedure for operation, the following elements should be considered:

a. Personnel cleaning prior to entrance (air showers, shoe cleaners, etc.).
b. Control of personnel headcount.
c. Cleaning of materials prior to entrance.
d. Control of special items used (paper, pencils, tote boxes, etc.).
e. Traffic control.
f. Layout of area.
g. Testing or inspecting materials and processes for the desired level of cleanliness.
h. Exposure time of the product.
i. Special apparel, change and laundering requirements.
j. Tools, tool cleaning and calibration requirements.
k. Special janitorial techniques.
l. Maintenance requirements.
m. Environment monitoring and reporting techniques.
n. Control of the use of cosmetics.
o. Use of pass throughs and communication media.

The clean room should be designed and maintained at the level required to assure product cleanliness, since higher levels of cleanliness than necessary may be as undesirable as lower levels. In order to assure continued and consistent cleanliness of the product, the parameters of the controlled environment must be monitored and

maintained. The control of personnel, processes, and environment is the principal factor in achieving the desired product cleanliness.

6.3 OPERATING PERSONNEL

For a contamination program to succeed, it is essential that the operating personnel understand the need for such a program. They must be fully aware of the consequences of their action or inaction as it affects the clean room environment and the product. A training or indoctrination program for all personnel is of primary importance, but the personnel that work within the controlled environment and come in intimate contact with contamination sensitive articles must be even more highly trained and motivated.

These individuals should be mature in their outlook and have a sense of responsibility toward their work. A sound orientation and education plan for personnel such as the one outlined in the following sections should be implemented to define the objectives of performing specific operations in the clean room. People will do a better job when they have a clear understanding of the engineering objectives in utilizing the controlled environment.

6.4 APPAREL

The subject of apparel is stressed to aid in recognizing, understanding, and controlling the considerable influence of clean room clothing in the environmentally controlled facility. The apparel worn by operating personnel in the clean room is the material most likely to come in contact with the hardware, work surfaces, or equipment. In use, the apparel becomes the medium for the transfer of contaminants such as lint, fibers, body ash, salts, flakes of skin, hair, and other debris. From the time clean room personnel don their uniforms, the migration of residual foreign matter into the cloth and the migration of contaminants from the body commences. This condition is further aggravated by functional processes and traffic in the clean room. It is reasonable to assume that, at some point, either hours or days (depending upon the activities involved), a saturation point will be reached; that is, a point is reached where the apparel is no longer reducing contamination, but is adding contaminants. Consequently, a scheduled change of apparel should occur prior to this point.

The state of the art in laundering clean room apparel has been advanced considerably, and clean room garments are now available that can meet very high cleanliness

requirements. It is important that these requirements be realistic and carefully evaluated for optimum results. For high levels of cleanliness the garment should be verified at this desired level when received from the laundry and prior to storage. A particle count is usually made by drawing air through selected areas of the garment and entrapping the entrained particles on a filter disc. A microscopic analysis of the filter disc is then performed which will indicate in a relative way the cleanliness of the garment.

Clean room apparel is currently available in several designs and materials from which a selection of any combination may be made to meet the specific needs of a given facility. Most of these materials are synthetics (nylon and dacron) because of their "limited linting" or relative "lint-free" characteristics. Of the two materials, dacron has become the most popular because of its low retention of static charges and resistance to yellowing with age.

One of the most significant characteristics of the clean room garment is the weave. Two different weaves, the herringbone and the taffeta, are in current use and each has a specific property which influences its application.

The herringbone weave has proved to be the more durable because of its relative heavy weight and density. For these reasons body contaminants originating from the wearer do not migrate through the material too readily, consequently the uniform can be worn for several days, dependent upon the nature of the processes in which the wearer is engaged. This same characteristic will also cause the apparel to be more difficult to clean. On the other hand, the taffeta weave can be laundered to a low particle count relatively easy; however, its useful life between cleanings is reduced considerably, since it will allow body contaminants to migrate rapidly. Such garments should be used for very meticulous operations that will justify a frequent change of apparel.

One of the major problems in current clean room apparel is the shoe cover. These covers tend to be dust traps and, in almost every case are loose and ill fitting; therefore, dust and dirt from street shoes worn underneath will migrate through such covers. A sneaker type shoe with vinyl soles and dacron or nylon uppers that can be laundered and worn in lieu of street shoes is an improvement over shoe covers. This also reduces the need for tacky mats and shoe brushes.

6.5 MONITORING THE ENVIRONMENT

Monitoring controlled areas is one of the main factors involved in their operation. Temperature, humidity, and positive pressures are usually monitored with direct reading instruments on a central panel located outside the controlled room. This location allows easy access to the panel for routine maintenance, servicing, and for checking and logging the environments being monitored. To minimize record keeping, these instruments are often equipped with 7- or 30-day recorders.

In those instances where several rooms are operating in series under different positive pressures, care must be exercised by personnel inside the room to insure that the pressure, which normally decreases linearly toward the entrance, does not change. A simple manometer at each door or other obvious location will facilitate this control. Checks on pressure drops across filters can be checked outside the facility by use of a portable manometer.

Dust or airborne particulate matter is the major factor to contend with, and several methods have been used to determine the level of airborne particles in clean rooms, all of which have specific advantages and disadvantages. The following listing indicates some of the methods used and a brief description of the techniques:

a. Impaction Method - This method allows a selected volume of air to be sampled by metering air at a specified velocity and allowing any particulates to be impacted upon a microscope slide. The slide is then placed under a microscope and analyzed relative to the number of particles and their size range. Investment for equipment is small, but actual analysis of samples is time consuming, and considerable skill is required.

b. Settling Method - A specified surface (petri dish or film strip) is exposed to the atmosphere for a period of time, after which any particles having settled on the surface are examined under a microscope to determine their count and size range. This method is of little value for particles smaller than 10 microns, since particles of this size usually remain in suspension. Investment for equipment is small (approximately $500); however, the time required for analysis is long and requires considerable skill.

c. Filter Sampling - This method employs a membrane filter disc and vacuum source and involves metering a given volume of air through the filter whereby all particles above a specified size will be impinged upon the filter surface. These particles are then counted and sized under a microscope, and the concentration is expressed in particles per volume of air. The technique

has been found to be effective down to the 5-micron level, but is impractical for clean room application below this size because of the time required for the counting. Investment for equipment is small, but considerable time is required for analysis. A major problem is encountered because of the background count on filter discs. To overcome this it is necessary either to precount the disc before use or to determine a statistical average for each lot of discs.

d. Impingement in Liquid - This method, commonly called the Greenburg-Smith technique, requires that a metered sample of air be drawn through a nozzle and the particulate matter in the air be impinged in a liquid, usually pure water. Subsequent analysis of the water indicates the level of particulate matter in the air. This technique requires a low initial investment, but requires considerable time and skill for analysis.

e. Condensation Nuclei Detection - This method is accurate, especially in the small particle size ranges. The function of this equipment depends upon the ability of water vapor to condense on submicroscopic nuclei which are then detected. The equipment registers quantity of particles only; it cannot differentiate particle type and size. The equipment involves a rather large investment, but very low operating and analysis cost.

f. Light Scattering - This method allows sampling and analysis to be performed at the same time, or it may be used for continuous monitoring in real time. Digital in nature, the equipment monitors a given volume of air passing through a focal point of a specially designed optical system. Each particle scatters light, and the intensity of this phenomenon is measured with detectors. This is a function of the size and distribution of the sample, and the concentration is indicated through a direct readout, printout, or both. This type equipment requires a high initial investment ($6,000 to $10,000) but has a very low operating cost, with a minimum of time required for analysis.

Stated briefly, the manual particle count techniques (impaction, filtration, impingement, and fallout) require low initial investment ($250 to $600), but involve a high cost of operation. The automatic techniques (condensation nuclei detection and the scattered light) require high initial investments ($3,500 to $10,000) with a relatively low operating cost.

The standards and specifications most commonly used require filter sampling as the standard method for counting particles greater than 5.0 microns, and light scattering as the standard method for counting particles between 0.5 and 5.0 microns.

The light-scattering technique has been criticized because absolute calibration of the instrument is not possible, and particles larger than 10 microns are difficult to count with the instrument, since they fall out quite rapidly or may become lodged in the sensing tube (the longer the sensing tube the greater the problem). The machine does establish conditions in a relative way and indicates changes as they occur; consequently, it can be considered an efficient and effective method for particle counting up to the 10-micron range. Attempts to check the accuracy of the instrument with other methods have indicated that this type of equipment produces counts on the high side rather than on the low side, thereby allowing the operator a reasonable degree of confidence.

Manual counts, on the other hand, have significant limitations because it may take hours before the results of the sample are known. In addition, skilled laboratory technicians are required to conduct the actual count and analysis, and as much as a 35-percent variation can occur in the analysis of a given filter when subjected to interpretation by two different technicians. In other cases it has been found that large particles (5 microns and up) which have evolved as a result of agglomeration tend to break up on impact with the filter and, as a result, may never be counted. In general, no matter what method is used, the count only determines relative conditions and rather than indicating a true count, changes in particle concentration are the significant information.

For any method of sampling and counting, it is very important that background and extraneous contaminants be taken into account to prevent misreadings. The method used should be selected with reasonable consideration given to economy and effectiveness toward the objectives of the facility involved. In the case of large multi-room facilities, the cost of technical support to perform manual counts may be prohibitive, but a minimum of such counts will be required to check periodically for large particles. If no concern is given to particles of less than 5 microns, or if a small facility is involved, periodic checks with manual counts will be sufficient. If there is concern for particles less than 5 microns, a combination of methods may be utilized.

Airborne particulate levels are in a dynamic state at any time in the clean room; consequently, any count obtained is applicable to that point in time and space when the

sample was taken. Continuous monitoring at several points, either with automatic or manual techniques, is impractical and unnecessary except where unusually stringent controls are needed. The accepted practice is to select typical points where samples are to be taken and conduct scheduled counts. A chart or graph of these counts is maintained that indicates the operating condition and history of the facility. This chart is compared to a series of charts that were prepared at initial startup of the facility for the given processes and loading of the facility. These charts are developed from studies made over a representative period of days and indicate the conditions to be expected at critical periods during the day and the time the highest concentrations can be expected (shift change, break periods, etc.), as well as the period of lowest concentrations achieved under stabilized operating and static conditions. This approach of developing the monitoring procedure based on historical operating data has proved effective. In addition, it gives an insight of the limitations of the facility relative to operations, processes, and influence of personnel.

6.6 GENERAL MAINTENANCE

The industrial clean room maintenance program should be developed with the same objectives that are used for other machinery and equipment falling in the category of capital investment, plus other considerations, such as janitorial services. The program should give cognizance to the functions, limitations, and operating characteristics of the machinery and equipment in relation to the impact of a shutdown or out-of-tolerance condition of the facility.

Close surveillance, inspections utilizing form checklists, and maintenance of accurate records will facilitate operation, cost control, and rapid accumulation of experience in operating the facility. An estimate of the over-all efficiency and operating costs of the clean room may be obtained by comparing the maintenance costs, with those for computer rooms, laboratories, chemical processing, painting, or for other facilities equipped for special operations that require unusual maintenance.

The unique construction and functional requirements of industrial clean rooms are such that serious operational problems and costly shutdowns can occur unless a carefully conceived and planned maintenance program is introduced and implemented early in the design stage of the facility. This action will not only provide protection to investment in the facility, but will reduce over-all maintenance costs of routine operations as well. With this approach, the clean room operation can develop a total maintenance program that is economical and can increase the useful life of the facility.

6.7 PREVENTIVE MAINTENANCE

A sound preventive maintenance program will help eliminate unscheduled shutdowns and will contribute significantly to the continuous operating economy and integrity of the facility. When implementing a preventive maintenance program the following should be considered:

a. Spare Parts - Insure that an adequate supply of spare parts is on hand for replacement and repair of special equipment, such as the vacuum systems, shoe cleaners, air showers, filters, etc. Parts lists should be checked for interchangeability of parts carried as standard equipment.

b. Equipment - A file should be maintained for special clean room equipment and tools. The file should include special instructions, parts lists, and nearest suppliers of this equipment. A periodic check should be made to insure availability of spare parts.

c. Personnel - Maintenance personnel should be familiar with both the inside and outside of the industrial clean room. They should receive the same orientation on clean room conduct as the personnel assigned permanently to production work in the facility. Where possible, the same maintenance personnel should perform the routine maintenance tasks in order to become familiar with the location and general characteristics of equipment, thereby gaining the advantages of continued experience and specialization.

d. Records - A simple record form similar to those used for other equipment giving the date, nature of the repair, and other pertinent information involving any maintenance should be utilized by the Maintenance Section to facilitate the rapid review of the clean room equipment performance and operating costs. A routine report should be issued periodically indicating costs of operation and possible methods of reducing these costs.

e. Inspection - Scheduled inspections should be made periodically to prevent unforeseen deterioration or other malfunctions which might lead to a major shutdown of the facility. A simple checkoff list will suffice for most of the major items or special equipment used for processing. These reports should be accurate and kept for a reasonable length of time as a reference.

6.8 JANITORIAL SERVICE

Cleaning of the equipment, furniture, etc., in the clean room must be done on a regularly scheduled basis. Some items within the facility may require cleaning several times a day, or even continuous cleaning, while others may require only monthly cleaning. This depends upon the several factors that create the need for

cleaning. In any event, the janitorial service must be a scheduled, planned function that will insure the integrity of the controlled environment.

Historical data obtained by monitoring the clean room environment can be used to develop and refine a janitorial plan that will give the desired results. The frequency of cleaning, time of cleaning, and janitorial personnel are of major importance, since processes and operations vary along with the number of shifts worked each day. Ideally, the optimum time for routine cleaning is when the facility is empty of personnel and no operations are being performed. Janitorial personnel should be oriented to clean room requirements and work to the same rules as the clean room supervisory and operating personnel. Cleaning operations should be reduced to a routine that can be followed with a checklist.

Excessive contamination or heavy concentrations of dirt will not normally occur in the clean room. Consequently, most cleaning can be accomplished rapidly by a vacuum cleaner and by damp cleaning with mops and sponges which will prevent scratching, scarring, and marking the walls and floors. Window cleaning can be accomplished with commercial window cleaning fluids. Use of aerosol and spray-type containers must be avoided because they inject particulate into the air. Because of various types of clean rooms and processes involved, no single standard can be considered applicable for all, but the foregoing can be considered the essentials of a basic plan for beginning operations. Subsequent adjustments can be made to increase or reduce the effort as indicated by operating history.

SECTION 7

PERSONNEL SELECTION AND TRAINING

SECTION 7

PERSONNEL SELECTION AND TRAINING

7.1 GENERAL

The contamination control program is not an end in itself. Cleanliness serves only to assure the successful function of the product. It is a factor that is prescribed by design and is achieved and maintained by all subsequent activities until the end use of the item. Although every sequence or element during the life of the product is a vital consideration, if there is a single most important factor it is the personnel involved with the product. People are the common denominator for all activities concerned with a product and are, therefore, the common denominator for contamination control. The degree of success of a program can always be related to how well the personnel performed.

The effect of personnel may be greater in a contamination control effort than in any other industrial activity because cleanliness is not always visible and a deviation is not readily apparent. To a large extent, cleanliness can be attributed to the honesty and integrity of the worker; therefore, the careful selection of personnel that work with highly sensitive components is of utmost importance.

7.2 SELECTION OF PERSONNEL

In selecting personnel for a critical operation, the first consideration is to be assured of the ability of the individual to perform the operation. Second, if the product requires high orders of cleanliness, it is obvious that just the ability to perform the operation is not enough. The worker must be able to do his work in such a way that the essential cleanliness of the part is not compromised. Because every action and inaction on the part of the worker may have an influence, each individual must be highly motivated toward contamination control. Since the achievement and maintenance of cleanliness often is not obvious, or even visible, an individual may create a violation unknowingly and unintentionally that may result in costly rework or part failure.

Each person who comes in contact with contamination sensitive articles must meet two basic requirements:

a. Be motivated to achieve and maintain cleanliness.

b. Be knowledgeable of contamination control principles and aware of the consequences of each action or inaction.

Motivation of personnel in an industrial activity is a study by itself and many volumes have been written on this subject. No attempt will be made to explore motivation beyond stating that the presence or lack of motivation is readily detected by able supervision. If there is lack of motivation, supervision will normally respond to the need with personnel counseling or other appropriate measures. Until the desired degree of motivation is assured, an individual cannot be considered qualified to become involved with a contamination sensitive activity.

This is not to say that only highly motivated, well educated and disciplined personnel can be safely used in handling contamination sensitive hardware. The workers are selected first of all for the other attributes identified as necessary to the operation. After selection of workers on that basis, the instruction and training in contamination control techniques can proceed as appropriate to meet the critical requirement of the operation.

7.3 TRAINING

Proper training of all personnel who may take part in contamination control efforts is usually the first phase of the program that should be implemented. If it is a new requirement, the training and instruction of personnel may be accomplished concurrently with the construction of the facilities. Generally, this will involve two or more levels of training. The first level is a simple instruction program to point out the need for, and consequences of, contamination control, and to familiarize the individual with the general practices and techniques involved. In some instances, because of a relatively simple product with a low level of contamination sensitivity, this may be an adequate training program.

In a program that requires the installation of a clean room or processes items that are highly contamination sensitive, the personnel who come in contact with these articles should be further trained and qualified. It is not essential or usual that a higher labor grade be employed; but, a different concept of operation than the normal shop activity exists and the worker must be trained accordingly. The extent of the training program should depend upon the nature of the operation.

The primary training effort may involve 4 to 6 hours of instruction; the secondary training for selected workers may require an additional 1 to 2 days of instruction. It is beneficial to require a simple qualifying test after each training phase to assure an understanding of the lessons, and to emphasize the importance of the classes.

The length of the course and the points of emphasis for instruction may vary between industries and products. The training program must be developed to a particular need rather than to a general plan to fit all requirements.

There are commercial interests that have developed comprehensive training programs in contamination control to train individual operators or give a specially oriented lesson plan for instructors and technicians who may then develop and conduct a course. Such a contract training plan may offer the best solution and is worth considering. Several methods and training approaches are in use today, ranging from the comprehensive training program conducted by an outside contractor to the simple "buddy" system used for training new personnel on some job classifications.

Where routine training for a given skill is desirable, a simulated clean room is sometimes used to implement clean room operational training concurrent with the development of other skills. In the case of a single employee being added to the clean room work force, a discussion with the supervisor in charge, covering the general and specific rules and regulations, may be sufficient, since the new employee will be under considerable influence of the older employees with whom he is placed. Qualification tests may still prove beneficial even for an individual trained in this manner. By and large the first condition, that is the orientation and training of a current work force, is the most common situation.

7.4 LESSON PLAN

The following is an outline of a lesson plan that has proved to be effective and may be helpful in developing a training program. The plan as outlined normally will require one day including the demonstrations, but may be expanded or abbreviated and delivered in several periods as deemed appropriate. During delivery of the plan, elaboration of each of the points can be achieved by various lesson aids such as pictures, charts, etc., guided tours, and other proven devices.

a. Contamination Definition

Contamination is defined as the presence of any foreign material referenced against absolute purity. This material can be ordinary dirt, corrosion products, oxides, industrial dust, vegetable spores, fibers, pollen, chemical products, or any organic or inorganic matter which adheres to, comes to rest on, or diffuses into the reference material, part, or medium.

b. Reason for Contamination Control

Discussion - safety aspects, national resources at stake.

Examples:

(1) NASA - Established contamination was one of the major causes of electrical, electronic, and mechanical failures on the Mercury program.

(2) Bell Laboratories - Gyroscope development at Bell Laboratories deals in tolerances of one ten-millionth of an inch; the tiniest amount of moisture or dirt cannot be tolerated.

(3) MSFC/NASA - Valves and control devices require frequent disassembly and reservicing as a result of contamination.

Forty percent of the failures and aborts on the early missile and rocket programs resulted from manufacturing errors of which half were attributable to contamination.

(4) NAA and MIT - Reliability in guidance and control would be difficult, if not impossible, to achieve in view of the tolerances required. Some of these parts have tolerances on moving parts as low as 1 to 25 microns and consequently could not be worked without a clean room.

c. Philosophy of Contamination Control

(1) A beginning-to-end concept - from the design phase to the end use of the item.

(2) The need is determined and prescribed at the design level; subsequent activities achieve, verify, and maintain the desired level of cleanliness.

(3) Personnel are the critical single element in a successful contamination control effort.

(4) Contamination control is not new but has recently become more important.

(5) Contamination control involves all aspects of an industrial activity.

d. Typical Kinds and Sources of Contamination

(1) Internal.

(a) Machining operations and operating machinery.

(b) Packaging materials and paper work.

(c) Assembly operations soldering and wiring.

(d) Lubricants.

(e) Traffic - any activity sets residual dust in motion.

(f) Welding, burning, etc.

(g) Buildings - particles released by vibration and shock.

(h) Chemical processing.

(2) External.

(a) Combustion products.

(b) Dust (airborne by wind, rain, etc.).

(c) Dust and other contaminants generated by automobile and other traffic.

(d) Construction activities.

(e) Industrial fumes (corrosive).

(f) Fungi, spores, bacteria, etc.

e. Nature of Contamination

(1) Problem of agglomeration.

(a) Static charges.

(b) Adhesion.

(c) Cohesion.

(d) Air currents and dead spots.

(2) Concentration.

(a) It is significant that a few particles of various compositions and sizes would not in most cases degrade or pose a potential failure for a given piece of hardware. The real hazard is the massive concentration of particles and fumes found in the atmospheric environments of the industrial community. In other cases, a single particle of 5-micron size may cause grief in some products.

(b) Particle concentrations range from 40,000 particles per cubic foot in rural areas to 1,500,000 particles per cubic foot in metropolitan areas. Sizes will range from 0.01 to 7,500 microns.

f. Techniques of Measuring Part Cleanliness

(1) Black light (ultraviolet light).

(2) Solvent wash.

(3) Microscopic examination.

(4) Gas "Blow Down."

(5) Non-volatile residue.

g. Controlled Environment Facilities

(1) Definition.

An industrial facility equipped to exclude external environments and maintain a maximum control over the internal atmospheric and general environments in which products are manufactured and/or processed, tested, and repaired.

(2) Examples of the use of controlled environment facilities.

(a) NAA

A 20° F temperature change will cause a 0.002-inch variation in a 10-inch aluminum ring.

(b) Chrysler Corporation

Chrysler found it necessary to build a 56,000-square-foot clean room to produce the current generation of automatic transmissions.

(c) U.S. Air Force

The Air Force standard clean room is effective for equipment with tolerances of 0.001 to 0.0001 inch. The current generation of airborne guidance and control systems could not be maintained and overhauled without clean rooms.

(d) General Electric

Placing critical AEC hardware production in clean rooms increased test yields 50 percent.

h. Operation of Controlled Environment Facility

(1) The clean room is equipped with the latest innovations for minimizing airborne particulate matter. The major problem will be control of processes and personnel. Consequently, extreme care will be required of all personnel assigned to or visiting the clean room to insure maximum performance from the facility.

(2) The state of the art in environmental controls has drawn heavily upon the medical and chemical sciences. Designs have now evolved that require a minimum of maintenance and control, but require personnel with a high level of maturity to insure that the room meets its end objectives.

(3) Personnel Restrictions.

(a) Restricted entry.

(b) Controlled storage.

(c) Scheduled entry and exit.

(d) Personal hygiene (nails, shaves, etc.).

(e) Control of cosmetics.

(4) Special equipment.

(a) Airshowers, tacky mats, and shoe cleaner.

(b) Communications equipment (intercom)

(c) Special apparel

- Synthetic materials.
- Special designs (fasteners, hidden seams).

- Special laundering and packaging techniques.
- Testing (define check points and techniques).
- Gloves.

(5) Special janitorial service, equipment and material.

(a) Plastic pails and waste containers.

(b) Cellulose sponges.

(c) Synthetic mops.

(d) De-ionized water.

(e) Anti-static detergents.

(f) Static retention fluids for dry wipers.

(g) Vinyl vacuum hose.

(h) Tacky mats.

i. Major Design Features of a CEF

(1) Positive pressures (linear reductions).

(2) Four-stage filter system (dust and hydrocarbons).

(a) Rough filters.

(b) Second stage 45 percent efficient.

(c) Absolute 99.97 percent efficient.

(d) Charcoal (hydrocarbons, fumes, etc.).

(3) Airlocks and pass throughs.

(4) Air conditioning for temperature and relative humidity control.

(5) Special tools and packaging materials.

(6) Circular or round structural shapes used where possible.

(7) Special designed or institutional (medical) type utensils, cabinets, and closures used where required.

(8) Special finishes.

(a) Stainless steel/anodized aluminum.

(b) Plastics.

(c) Smooth surfaces.

(d) Epoxy and urethane paints.

(9) Special enclosures.

(a) Unified work stations.

(b) Writing stations.

(c) Laboratory area.

(d) Pass throughs.

As pointed out, this lesson plan may not fulfill every need; it is considered only a minimum outline. The plan is included merely as a guide to suggest a course of instruction.

SECTION 8

CLEANING

SECTION 8

CLEANING

8.1 GENERAL

Within the scope of the contamination control effort two types of cleaning may be considered. They are gross or rough cleaning and final or precision type cleaning.

As the name implies, gross cleaning includes all those cleaning operations that are intended to remove heavy deposits of contaminant material such as scale, rust, metal chips, shop dirt, and other forms of unwanted substance. Gross cleaning can be accomplished by either mechanical or chemical means. Some of the typical mechanical cleaning methods are:

a. Wire brushing.
b. Shot blasting (wet and dry).
c. Grinding.
d. Sand blasting (wet and dry).

Generally, mechanical methods are the most useful for removing heavy or particularly unyielding materials. For most purposes, chemical cleaning is the preferred approach because mechanical methods usually leave foreign deposits on the part which necessitates additional treatment by chemical means.

There are four categories of gross cleaning by chemical means:

a. Acid pickling - various acid solutions are used to remove scale and oxide and for passivation of different metals and metal alloys. This category would include the electrocleaning processes.
b. Alkaline cleaning - metallic components which have fine tolerances that may be etched or damaged by acid pickling are usually descaled or cleaned by alkaline solutions.
c. Detergent cleaning - most useful with plastic materials for removal of grease and shop dirt. The detergent is often used in conjunction with steam or pressurized tap water.
d. Solvent cleaning - used chiefly to remove hydrocarbons and entrapped dirt from metal parts. The solvent is used in either a cold bath, a spray, or vapor degreasing. This method is faster than detergent cleaning and can usually be done in one step.

Various combinations of chemical and mechanical cleaning methods are utilized as the optimum cleaning process. Table 8-1 is a cleaning chart taken from the Air Force T. O. 42C-1-11 that shows typical precleaning or gross cleaning for a variety of materials.

The gross cleaning processes may be considered as normal factory operations. They are found in the heaviest of industries that are not necessarily concerned with the concept of contamination control beyond good housekeeping or normal shop practice. Gross cleaning methods are of concern because they usually make subsequent cleaning operations more effective, reduce contamination of the final cleaning solutions and processes, and prevent contamination of controlled environment areas. A thorough discussion of gross cleaning methods may be found in any handbook or manual of metal finishing or electroplating. *

The need for higher levels of cleanliness has made it necessary to develop new techniques for precision cleaning. There are many final cleaning processes that have evolved to insure that the subject article achieves extremely high cleanliness levels prior to packaging closure or sealing. The precision cleaning operations are always subsequent to gross cleaning and are usually performed in an environmentally controlled facility to permit enforcement of the prescribed cleanliness level.

8.2 CLEANING SOLUTIONS

Precision cleaning is usually accomplished by the use of solvents, detergents, or high-pressure inert gas purge. The solvent method is the most widely employed as it lends itself to a large variety of materials and a number of different processes. Basically, solvents are used to dissolve soluble material and because they are fluid they will tend to suspend and flush away insoluble material.

There are many kinds of chemical agents that may be classified as solvents; however, the group of chemicals known as organic solvents is the most useful and versatile for precision cleaning of components. Organic solvents include the ethers, alcohols, ketones, and halogenated hydrocarbons.

*The Metal Finishing Guidebook Directory, published by Metals and Plastics Publications, Inc., 99 Kinderkamack Road, Westwood, New Jersey 07675, is extensively used as a reference.

Table 8-1

Selection Chart for Cleaning Processes

NOTE

(1) Symbols in the block denote a recommended process for the surface condition indicated, and will normally be accomplished in consecutive order from left to right.

*(2) Trichloroethylene shall not be used for cleaning elastomers.

Material	Surface Condition	Precleaning Processes															
		Mechanical Descale	Degrease	Alkaline Clean	Tap Water Rinse	Detergent Clean	Tap Water Rinse	Phosphoric Pickle	Tap Water Rinse	Chromate Dip	Tap Water Rinse	Pickle and Passivate	Tap Water Rinse	Demineralized Water Rinse	Drying	Preparation for Clean Room Entry
Aluminum, brass bronze, copper	Bare or machined, free of heat oxidation		X	X	X									X	X	X
	Anodized or chemical film coating		X		X	X								X	X	X
	Weld scale, corrosion, or heat oxidation	X	X	X	X									X	X	X
Stainless steel	Free of scale		X	X	X									X	X	X
	Weld scale, corrosion, or heat oxidation	X	X	X	X							X	X	X	X	X
Carbon steel	Free of scale		X	X	X					X	X			X	X	X
	Weld scale, corrosion, or heat oxidation	X	X	X	X			X	X	X	X			X	X	X
Non-metallic parts, elastomers*	As received					X	X							X	X	X
Electroplated parts and dissimilar metals	As received		X	X	X									X	X	X

The choice of which solvent to use for a particular application is dependent upon a number of factors. The following are the primary considerations:

a. The solvent must be capable of removing contaminants by dissolving them or washing them away.
b. The solvent must not damage the part to be cleaned.
c. The evaporation rate and temperature at which the solvent is used must be considered.
d. The hazard of the operation (toxicity, flammability).
e. Economic consideration.

The larger chemical suppliers have data on their proprietary, as well as common, solvents that may be helpful in selecting an optimum solvent and process for a particular application.

Detergent cleaning solutions are being widely used for precision cleaning of some parts, particularly plastics. The detergents act like the solvents in that they remove oil type deposits and float away insoluble contaminants. They may be used on materials that are sensitive to the solvents and have the advantage of low toxicity, nonflammability, low evaporation and can be used at a higher temperature for more active cleaning. Detergents are removed by water rinse followed by a high purity water rinse to practically eliminate residue. In general, the detergent solutions are less expensive and are more versatile in use than solvents. They may be used effectively in cold cleaning applications, in a high velocity spray, in ultrasonic cleaners, or in flush cleaning applications.

The main disadvantages in the use of detergents are that they require a relatively high degree of rinsing to remove all traces of residue and do not dissolve deposits of film as readily or quickly as solvents. Because water is the basis for the solution, parts cleaned with detergents require either heated air (or inert gas if corrosion is a problem) for rapid drying or the rinse water must be displaced with a solvent. In addition, detergent solutions (or their water content) may not be compatible with some materials or articles to be cleaned.

The decision of whether to use a solvent or detergent for cleaning must be determined for each situation. The solution and the process to use will depend upon all the variables of material, configuration, cleanliness level, kind of soil, economy, degree of precision, etc. However, the selection of the solution and process to use will have a

severe influence on the ultimate cleanliness. Whatever choice is made, process control is of paramount importance to assure that the desired cleanliness is achieved and maintained.

8.3 COLD CLEANING

There are various methods of employing solvent or detergent solutions for the removal of contamination. The first and simplest method is to wash the part in the solution. This method is usually referred to as cold cleaning. Quite often it is adequate for some requirements; however, it may not be enough for precise cleaning. When using a single solvent bath, it is obvious that once a part has been cleaned, the solvent has then become contaminated with soil from the part. The next part cleaned will be withdrawn with a film of solvent on it and the residue contained in the solvent will remain after drying. Each successive part worsens the condition. This may be overcome to some extent by utilizing several successive baths and by changing the solvent often. This condition does not present the same problem with detergent solutions because they are always followed by extensive rinsing.

Quite often cold cleaning with slight agitation is all that is necessary to achieve the desired results. This method is highly satisfactory for the removal of light soil. For the removal of more adherent soil it is a common practice to use a fibre brush to scrub the part with solution. Mechanical scrubbing is helpful to remove insoluble particles that may be trapped or embedded in the part. The essential point to remember when cold cleaning in solvents is that, once used, the solvent has become contaminated and may no longer be useful for precision cleaning.

Used solvent, however, need not be discarded. There are several devices that can be obtained or constructed for the filtration and distillation recovery of used solvents. These devices have proved successful and economical, especially for large quantities of solvent.

8.4 VAPOR DEGREASING

A widely used technique for precision cleaning is vapor degreasing. The basic principle that makes this process desirable for final cleaning is that the cleaning is done by a solvent that is free of non-volatile contaminants. As the work is exposed to the solvent vapor, the vapor will condense on the part (which has a lower temperature) to wash away oils, soil, and other contaminants. When condensation has ceased, the cleaning action is finished and the part can be removed, clean and dry.

There are many variations of vapor degreasing machines. These range from small bench type units for small parts to very large machines for large or bulk items. These machines can incorporate several features that have specialty applications; however, they all employ the same basic principle of condensation of solvent vapors on the part. Vapor degreasing may be unsuitable for cleaning heat sensitive components. This limitation is often overcome by selecting a solvent that has a low boiling point. Obviously, vapor degreasing cannot be used on solvent sensitive items.

8.5 SPRAY CLEANING

Another technique of precision cleaning is to direct a high velocity stream or spray of solution onto the part. There are several commercially available machines that employ this principle and they are very effective cleaning devices. Normally, for small parts, the part is loaded into a basket or holding fixture that exposes all surfaces to the spray of solution during a cycle of the machine. In some cases, for large tanks, etc., a specialized machine may be developed. Spray cleaning of vessels or tanks in a vertical position has proved very successful. This technique has the advantage that the mechanical action of the spray effectively scrubs or tears contaminants loose from the part and washes them away. A wide variety of solvents or other cleaning solutions can be used effectively. However, this method has the same disadvantage as cold cleaning; once the solvent is used it becomes contaminated and may leave a residue. This may be overcome by successive use of clean solvent rinses, careful process control, and solvent filtering.

8.6 ULTRASONIC CLEANING

A widely used process for precision cleaning uses ultrasonic energy to impart mechanical action into the cleaning. Ultrasonic energy is very effective in dislodging tightly adhering particles that are insoluble. The action depends upon the creation of tiny (usually invisible) bubbles in the solution that explode (or implode) against the part to effect a mechanical scrubbing action. Again, the solvent becomes contaminated after each use; however, this disadvantage has been overcome with some of the recently developed equipment that includes distillation apparatus to continuously supply clean solution to the bath.

Ultrasonic cleaning equipment is available in a wide range of sizes and types. Small bench top units are most often used for precision cleaning; however, large bulk type machines are not uncommon. All types will operate well with a wide selection of cleaning agents. The choice of the cleaning agent is extremely critical for optimum operation.

Besides the size limitations and critical adjustments required by the equipment, there are, in general, two major limitations to the use of ultrasonic energy. First, it does not materially contribute to the cleaning of resilient materials that will absorb the energy and is, therefore, of little use in cleaning soft plastics, rubber, and fibrous material. For such material the ultrasonic energy only serves to mildly agitate the solution and is comparable to the cold cleaning method. The second major limitation is that ultrasonic energy has been found to degrade some sensitive components. For instance, semiconductor devices (transistors and diodes) are often rendered useless after ultrasonic cleaning and some metal plating or finishes may be damaged. Careful selection of the operating frequency, the solution used, and the amplitude of the ultrasonic energy will help reduce these negative effects and will enhance the cleaning action. In considering solvent or detergent solutions, it is an important factor to remember that the cleaning energy at the part is much greater in water than in solvents.

8.7 FLUSH CLEANING

A type of precision cleaning that is widely used for missile components is flush cleaning. This is often the only way of removing contaminants from some tubes or lines, tanks, vessels, etc. The flush cleaning method may be useful for either components or complete fluid (liquid or gas) handling systems.

Flush cleaning involves passing a fluid through the component or system to remove the contaminants from the interior walls. The cleaning system can be either open end, which uses a single pass of cleaning fluid, closed loop which circulates the fluid, or closed end which involves filling, agitating, and dumping the solution. Usually a filter is placed in the fluid line just prior to the point that the fluid enters the component or system. This will help insure clean (particle free) fluid for cleaning.

Flush cleaning depends upon the ability of the cleaning fluid to dissolve the films and to wash away the insoluble contaminants. It must be pointed out that insoluble particles tend to adhere to the inside walls because of various adhesive and cohesive forces. These forces are not normally overcome by simply passing a fluid through the system, as is done by the open end or closed loop method, because it is a basic physical law that a fluid flowing through a line has zero velocity next to the wall (the velocity increases toward the center). Simple flushing cannot be counted upon to remove particles adhering to the wall of the component or system. Increasing the pressure of the fluid will probably not contribute materially to the cleaning action. Further, if there are changes in the configuration of different sections of the system being flush cleaned, they will create turbulence areas and dead spots (zero velocity) at the point of change.

In order to overcome the effect of zero velocity next to the wall and to develop a scrubbing action within the system, the pressure head can be increased and decreased. At each change of pressure a turbulence will be created that moves through the system. At the point of turbulence the zero velocity will be offset and a resulting scrubbing action will be realized.

Another method of causing the particles to come free of the walls is to impart mechanical energy into the wall itself to effectively vibrate the particles loose. This can be done by immersing the component or system in an ultrasonic bath during the flushing, by moving an ultrasonic transducer along the outside wall of the line or vessel, or simply by tapping the walls with an impacting device. The approach used in the closed end method is to impart motion or rotation to the vessel to cause agitation of the fluid. In addition, for all methods of flush cleaning, all movable parts in the system should be actuated several times during cleaning. In general, flush cleaning is not as effective as other cleaning methods (spray cleaning) and is used with known limitations.

A high pressure gas purge may be thought of as another form of flush cleaning. In this case the fluid used is normally dry, clean nitrogen. The same principles apply inasmuch as mechanical energy is necessary to insure that the particles are broken free from the walls. Gas purge is not as effective as a liquid solution flush and for that reason finds its greatest use as a secondary process to remove water vapor or similar contaminants. In general, it is considered a poor method if used by itself.

Whatever cleaning method is employed, rigid quality control of the cleaning agent is very important. The cleaning solution must be free of any material that may deposit on the cleaned item. Restrictive purchase specifications must be used to insure that the suppliers of the precision cleaning solutions deliver only high purity, carefully controlled material. The cleaning fluid must be carefully tested for non-volatile residue and particle count when it is received.

8.8 SOLVENT STORAGE

Storage provisions for precision cleaning solutions should provide nearly constant temperature to prevent the containers from "breathing" with temperature variations. The container should be protected so that moisture or dirt does not accumulate and possibly find its way into the handling containers. Handling containers, piping, tanks, etc., must be carefully chosen so that the material from which they are made will not leach out or otherwise contaminate the precision fluid.

Most suppliers can deliver "ultra-clean" cleaning fluid. However, as a precaution it is advisable to filter the solution before use because solvents can become contaminated from handling and storage (this may be modified based on individual experiences). In any case, the user must exercise care in order to assure cleanliness at the time of use.

8.9 MONITORING AND INSPECTING FOR CLEANLINESS

In order to be sure of the success of a precision cleaning operation, it is necessary to develop reliable, accurate monitoring and inspection techniques. This poses many problems because the cleanliness limits must be defined in real terms and contamination is not simply detected.

The only realistic way of monitoring cleanliness is to detect and measure contamination (or freedom from contamination) on the part. There are several methods of accomplishing this of which three are most commonly used:

a. Direct microscopic inspection.
b. Solvent wash.
c. Gas purge or gas blowdown.

Each method will have different applications. Of course, these techniques presuppose that normal visual inspection has been applied.

Direct microscopic inspection is the simplest, most direct and most effective method. In this case the surface of the part is examined under magnification by a trained operator. A particle count is made of detectable particles. Special lighting techniques such as high incident lighting may be used to cause contamination to become more apparent. Black light (ultraviolet light) may be used to cause fluorescence of most hydrocarbon residual; however, black light should not be depended upon unless the kinds of contaminants of concern are known to fluoresce.

Microscopic inspection may be used for small parts or representative sample areas of large complex parts. The major limitations to this method are that it does not lend itself well to complex configurations or hidden surfaces; it normally requires several readings to be averaged in order to develop a high-confidence measurement; and it requires a high degree of skill on the part of the operator. This method is most useful for flat surfaces and lends itself to either sampling or 100 percent inspection.

Solvent wash is adaptable to measuring contamination levels of any item that can be washed by a solvent. In this method, a measured quantity of solvent of a known cleanliness is used to wash the part (ultrasonic energy is often used to enhance the cleaning). The solvent is then collected and passed through a filter disc that collects the entrained particles. The filter disc is then analyzed under magnification to determine the particle count relative to the washed area. By a comparative weighing of the residue after evaporation of used and unused solvent, a determination of the non-volatile (hydrocarbons, etc.) contaminants can be made.

The solvent wash method of contamination measurement is highly versatile. By careful selection of the solvent, it can be used for most materials. However, it is a time consuming process and depends upon very rigid disciplined control to prevent extraneous contamination from causing a misreading.

Gas purge or gas blowdown is often used in field applications. The equipment and material to perform this test are available in portable kit form. The test is sometimes used for determining the cleanliness of fluid systems or components. However, some activities have found this to be an unreliable system and do not permit its use.

The test proceeds by connecting a "bomb" or source of pressurized clean gas such as dry nitrogen to the inlet side of the system or component. Normally a filter is placed in the inlet to insure that particle free gas will enter. A filter is connected to the discharge or exhaust end of the system. The gas is allowed to flow through the system at a given pressure for a given volume. The filter disc at the exit will collect any particles entrained by the gas. The filter disc is then examined microscopically to determine the particle count.

A series of small bottles of filtered carbon tetrachloride or another solvent are connected in series to the exit of the system. The exit gas is then successively bubbled through the solvent. This gas scrubbing removes the hydrocarbon content from the test gas, and the hydrocarbon content is then measured by evaporating the scrubber solution and weighing the residue.

This method of measuring cleanliness has the advantage of portability. However, comparison with the fluid wash method indicates that the gas cannot be depended upon to entrain solid and hydrocarbon contaminants.

Other specialized types of measurement procedures have been developed for particular applications. Commercial devices are available to monitor continuously on-stream fluids; a radioactive tracer system has been developed that depends on the evaporative rate of contaminated surfaces that may have application in measuring extremely low levels of organic, inorganic, and soluble contaminants; in other cases the work is purposely "salted" with a radioactive contaminant whereby the radioactive residue can be measured after cleaning to determine the relative efficiency of the cleaning process.

Various physical phenomena can be measured in relative terms that will indicate the presence of contaminants. There may be situations in which one of the following characteristics may be helpful in measuring cleanliness:

a. Acid/alkalinity of a surface.
b. Wettability of a surface - the contact angle of a liquid droplet on a surface indicates surface tension and relative surface contamination.
c. Spectrophotometric analysis.
d. Bacteriological techniques.
e. Ultraviolet detection.
f. X-ray diffraction.
g. Electrical conductivity.
h. Light scattering.
i. Changes in weight.

It is extremely important when sampling and measuring contamination levels that all precautions be taken to prevent reading extraneous contaminants. It is a common error, for example, to use a contaminated bottle to contain a fluid sample resulting in an erroneous reading. The need for a clean bottle or a bottle with a predetermined background count is an important requirement in this case.

The most important points to consider when developing techniques for measuring part cleanliness are critical type of contamination, the nature of the part, and the degree of accuracy and repeatability required.

SECTION 9

PRECISION PACKAGING

SECTION 9

PRECISION PACKAGING

9.1 GENERAL

Once a part has been cleaned and the cleanliness verified, it is necessary to preserve that cleanliness until the end use of the part. The obvious method for providing the necessary protection is by the use of packaging techniques. Specialized precision packing has been developed as a means of preserving cleanliness.

Precision packaging is not necessarily intended to provide physical protection to the component or system during handling, storage, etc. Precision packaging must be thought of as a development for the sole purpose of maintaining the part or material in a relatively contamination free state. Other conventional packaging methods may be necessary and are employed in the normal manner to provide the necessary physical protection and to assist in handling, shipping, and storage.

Within this concept it is necessary to think of a precision packaged item as an inseparable unit. If the precision package shows damage or violation, it is assumed that the part is contaminated and cannot be used. The essence of precision packaging is that a contamination sensitive item must always be protected from contaminating influences. The controlled environment facility may provide this protection during assembly, test, etc., but the precision package must succeed the function of the controlled environment.

Precision packaging must take place as soon as practicable after final cleaning and verification of cleanliness. Once final cleaning has been accomplished, the cleanliness of the item can only be degraded and all efforts must be made to reduce the degradation. Ideally, as soon as the item has been fully cleaned, it should be immediately precision packaged; however, it is not usually feasible to do this. In this event, a temporary protective cover, envelope, or handling box is used for interim protection, even within the controlled environment. For example, a major complex assembly may have the individual parts cleaned at different times over an extended period. Assuming that the assembly takes place in a clean room and that interim protection in the form of temporary parts covers has been provided, the finished assembly is considered to be clean. However, depending upon the contamination sensitivity of the assembly, the cleanliness should be verified concurrently with other final inspection requirements.

Upon acceptance, the assembly should be immediately precision packaged while still in the clean room environment but, where possible, the packaging area should be isolated from other activities.

9.2 SELECTION OF PACKAGING METHOD AND MATERIAL

Many articles that are precision cleaned are maintained as individual components. Most small individual items such as valve parts, bearings, O-rings, etc., can best be precision packaged in envelopes, bags, vials, bottles, etc., or other devices that will provide over-all protection. However, for many components such as tubes, cylinders, valves, and electronic or electromechanical assemblies, the precision packaging may involve only the closure or sealing of critical openings or entries. The case or body of the item provides the principal contamination barrier. In the event that the contamination sensitive item is completely encased while in the clean room (such items as potted assemblies, hermetically sealed electronic units, etc.), the case may provide complete contamination protection and precision packaging may not be required.

No fixed rules exist for precision packaging because these will vary from product to product. One thing that is common to all precision packaging is the need for clean packaging material. The precision packaging material may take almost any form:

a. Heat sealable plastic envelopes or bags.
b. Bottles, vials, cans, etc.
c. Bubble or blister pack.
d. Plastic film or metallic foil wrap.
e. Foil, film, covers, etc., for closures.
f. Tape, paint, sealants, bolts, etc., to aid in making closures.

The choice of material and the configuration of the precision package will, of course, depend upon the nature of the part. The most effective and economical means is limited only by the materials available and the creativity of the personnel.

Additional features that may be introduced into the packaging method are devices that will indicate the contamination sensitivity of the packaged article. Such devices should be positive indicators that will call attention to the need for cautious, careful, and proper handling. The following are some of the devices that may be employed:

a. Colored packaging material - different colors for different levels of cleanliness, cleaning procedures, or service use.
b. Specially designed labels.

c. Follower cards or tags on which to record significant information.

d. Unique or specially designed secondary pack (overpack).

Whatever packaging material and method is used, a common requirement is that the material shall be clean to the desired level and will not by itself generate contaminants that may degrade the packaged item. For instance, many plastic films have a tendency to slough particles. If a LOX (liquid oxygen) valve were packaged in such material the normal handling and storage would cause enough of the sloughed particles to accumulate on the part to create an explosive hazard or a failure when exposed to LOX. For this reason, material compatibility becomes a problem.

Since all materials slough particles to some extent, the selection of compatible materials is an important decision. An attempt should be made to choose the material which is least susceptible to sloughing and most compatible with the material and service of the part. Fluorocarbons (Teflon, kel-f, Aclar, etc.) will not react with LOX and are, therefore, widely used for precision packaging of LOX components.

Another consideration when choosing the packaging material and method is to avoid motion or abrading between the package and the item. The less the motion, the less number of particles will be generated. For this reason, an intimate wrap or blister pack conforming to the part may prove to be the most desirable. Aluminum, lead, or other metallic foil will wrap intimately to the contour of complex shapes; however, caution should be used since metallic foil is noted to be relatively high in shedding.

For the purpose of making closures on tubes, valves, etc., a plastic plug or cap obtained from commercial sources should be used cautiously because this method often results in particles of plastic abrading from the plug and getting into the system. If the design permits, a specially designed metal or plastic cover plate may be bolted or otherwise secured to close an opening. In some cases a plastic film may be formed over the opening and secured with various vinyl or epoxy sealants.

Often the precision cleaned part will be packaged in a pressurized container or a package charged with inert gas to prevent corrosion. In this case the package will of necessity be more involved and require special design. Usually this technique lends itself better to a secondary pack or overpack.

As much consideration should be given to the cleanliness of the package as is given to the cleanliness of the item; that is, the packaging material must be cleaned and the

level of cleanliness verified prior to use. There are commercial sources for plastic film, bags, and sheets, metallic foil, and other commonly used materials that will supply clean, certified material. Such sources may provide guidance in the selection of material and the development of a packaging technique. When purchasing clean material, verification of cleanliness, storage, and handling provisions become critical.

Sometimes sources of adequately clean material are not available or cannot be relied upon and it is necessary to establish a capability for precision cleaning of the packaging material or system adjacent to the final parts cleaning operation. The same precautions that apply to cleanliness of the part or system, must apply to the packaging method and material.

9.3 TAMPER-PROOF SEALS

After precision packaging has been accomplished, it is important that any violation of the integrity of the package will be detected. The package must be made as tamper-proof as practical since the package and the item are an inseparable unit, and damage to the package is presumed to be equivalent to damage to the part.

There are several means that may be employed to indicate violation of the precision package. Some of the most common methods are as follows:

a. Sealant material applied to a closure in such a manner that breaking of the closure will be indicated.
b. Safety wire and lead seal applied to a cap or plug.
c. Frangible (egg shell) decalcomania or seal.
d. Labels, stickers, or stamps across a seal.
e. A strippable coating applied over the precision package.
f. Pressure indicators for pressurized packages.

The purpose of the tamper-proof seal is to provide an inspection technique that will prevent the storage or use of contaminated articles and at the same time permit action to be initiated to reject or rework (reclean) the article. The use of such a device serves the secondary function of bringing attention to the sensitivity of the package and will result in more careful treatment and handling.

9.4 GUIDELINES FOR PRECISION PACKAGING

Although there are no set rules or procedures, the following list may be used as a guide or checklist to develop a precision packaging requirement:

a. Determine the optimum packaging material based on resistance to sloughing, compatibility with packaged item, and the service medium.

b. Determine the optimum packaging and closure methods (heat seal envelope, blister pack, wrap, can, or bottle, etc.). Items that are inherently sealed do not require precision packaging.

c. Provide for temporary protective packages and in-process handling containers.

d. Develop method for indicating precision packaging and level of cleanliness (color code, label, etc.).

e. Develop method for purchasing, storing, handling, etc. of clean packaging material.

f. Provide cleaning capability for packaging material where indicated.

g. Develop procedure for sampling and measuring contamination level of packaging material.

h. Develop tamper-proof seal devices.

i. Avoid vacuum packages as there is a tendency to "draw in" contaminants.

j. Do not tear open clean packages as the tearing action generates heavy sources of particulates. Develop a "clean" opening process.

k. Treat a precision packaged item as an inseparable unit.

l. Develop storage or inventory procedures that will assure the integrity of the package.

m. Provide protection, where indicated, beyond the precision packaging with a durable secondary overpack.

n. Design the package to allow the least possible relative motion between the part and the packing material.

SECTION 10

BIOLOGICAL CONTAMINATION

Note

The information contained in this section is based on an article prepared by The Biological Contamination Control Committee of the American Association for Contamination Control, entitled Microbiological Contamination Control - A State of the Art Report, Phillips, G.B., Ph.D., et al., 1965.

SECTION 10

BIOLOGICAL CONTAMINATION

10.1 GENERAL

The purpose of any contamination control effort is to reduce or manage contamination at the desired level. Biological contamination poses special problems in this respect because of the unique ability of living forms of matter to reproduce and grow. A specialized form of contamination control is needed to cope with the problem of living forms of contamination or "living dirt" as it is often called.

Many kinds of biological forms can cause problems in diverse situations. It is well known that there is a need for control of bacteria, fungi, virus, etc., in hospitals, and food processing and pharmaceutical industries. It is apparent that the formation of mold or fungus growth can cause problems in all industry by the destruction of materials. Commercial and military jet aircraft operations have been faced with a problem of living organisms surviving, reproducing, and forming colonies in jet fuel. The organisms will clog fuel lines and filters, as well as cause other serious effects from the by-products that they produce.

The variety of forms of these living organisms that cause these problems are referred to as microbiological or microbial organisms. A highly complex science composed of many subspecialties has grown in an attempt to study, understand, and finally control the effects of the variety of microbial life forms.

This discussion will present some of the tools, techniques, and procedures that have been developed and are used by the microbiologist to control the effects of living organisms.

10.2 NATURE OF MICROBIAL CONTAMINANTS

Microbial contamination may be defined as the presence of living microorganisms in a specified environment. In general, the microorganisms will be those classified as bacteria, fungi, virus, spores, etc., that exist in microscopic size ranges in various media such as water, air, fuel, soil, etc., and on various mechanical, human, food, or other surfaces.

Microbial forms of contaminants are similar to the particulate contaminants in that the organisms have structure and mass. The individual organisms may range in size from 0.2 to 10 microns. The characteristics that set them apart from particulate contaminants are their ability to reproduce, grow, and form colonies, and their ability to carry on physical and chemical processes. Microorganisms in a given population are normally going through a process of multiplication, growth, and death. It is apparent that under the effects of microbial contamination there are unstable, constantly changing conditions that require attention on a continuous basis in order to achieve control.

A tremendous variety of microorganisms exist on the earth, many of which have not been described. These microorganisms can utilize as energy sources diverse substances ranging from basic elements, such as iron and sulphur to the most complex of organic compounds. Some microbial species utilize atmospheric oxygen in their metabolism; others live without free oxygen. Microorganisms have a unique ability to survive under adverse environmental conditions. Spores, for example, represent a special form of microbial life that is more resistant to environmental influences than other forms. Moreover, mutational processes enable microorganisms to develop resistance or adapt to conditions of an adverse environment, as in the case of organisms that become resistant to antibiotics.

10.3 STERILITY AND DISINFECTION AS MEANS OF DECONTAMINATION

Insofar as microbial contamination control is concerned, the only condition that can be considered stable or final is sterility. Sterility is the absence of all viable (living, reproducing, growing, etc.) organisms - it is an absolute term. In the broad sense, a part, material, or medium may be contaminated by various agents and still meet the definition of sterile. On the other hand, a sterile part is free of living microbial particles but does not necessarily imply the elimination of dead cellular debris. In some highly specialized requirements, the debris of dead organisms may be a contaminant and cause problems because of chemical action of the residue, or because of its physical structure. However, in most practical applications, the dead cells or residue will present no problem and are seldom dealt with in a specific nature.

Because sterility permits a stable condition, sterilization has become an important technique in microbial contamination control; however, it is by no means a simple procedure and often is not attainable.

Practical problems arise for anyone employing routine sterilization procedures; that is, problems for which there may be no clear-cut answer. This is due to the fact that heat, the most reliable means of killing microbes, cannot be applied in many situations where the contaminants exist, such as in heat sensitive materials. Therefore, it often becomes necessary to resort to less reliable means of sterilization, or to accept something less than sterilization, generally referred to as disinfection or decontamination. Disinfection techniques as methods of decontamination are often completely acceptable when considering contamination control because they reduce the organisms to an ineffectual level.

Of the numerous physical and chemical means of sterilization, inactivation of microorganisms or decontamination, those that are most widely applicable may be classified under one of the following five main headings:

a. Heat

It is generally accepted that the application of heat, either dry or moist, is the most effective method of inactivating microorganisms. The exposure temperatures and times required for sterility are known and can be readily controlled. Whenever possible, heat should be used to decontaminate materials. All organisms succumb to heat at some level of exposure.

b. Vapors and Gases

A variety of vapors and gases possess germicidal properties. Among these are ethylene oxide, formaldehyde, propylene oxide, beta-propiolactone, and methyl bromide. When these agents are combined with the effects of temperature and humidity, excellent decontamination can result. Under controlled conditions, ethylene oxide is a highly penetrating and effective decontaminating gas, convenient to use, versatile, noncorrosive, and effective at room temperature. However, the gas is slow in killing microorganisms and must be mixed with other gases to avoid explosion hazards.

Ethylene oxide is widely used to treat many items not suitable for heat sterilization. Propylene oxide is slower acting than ethylene oxide but it presents less toxicity and flammability problems.

Formaldehyde and beta-propiolactone are used primarily as decontaminants for room and building interiors. Formaldehyde, the slower acting of the

*Approved dry heat sterilization cycles for spacecraft may be found in a U.S. Government memorandum entitled Sterilization Cycles, by Hall, L.B., NASA Planetary Quarantine Office, Washington, D.C.

two, has the undesirable property of leaving a difficult to manage residue. Beta-propiolactone holds great promise as an area decontaminant. In the vapor state, it acts rapidly against most microorganisms and has no adverse effect on most materials. It is much faster acting than formaldehyde and does not leave an undesirable residue after spraying. However, a serious deterrent to the use of this chemical is its toxicity.

Methyl bromide is about one-tenth as active against microorganisms as is ethylene oxide. The bromide has found greatest use in soil sterilization, especially to eliminate fungi.

c. Liquid Decontaminants

There are many misconceptions concerning the use of liquid decontaminants. This is due largely to a characteristic capacity of such liquids to perform dramatically in the laboratory under controlled conditions and to fail in a practical situation. Such failures often occur because too little consideration is given to such factors as temperature, contact time, pH level, concentration, and the presence of organic material at the site of application. Small variations in these factors may cause great change in effectiveness. For this reason, even when used under highly favorable conditions, complete reliance should not be placed on liquid decontaminants.

In the decontamination of large areas or rooms the mechanical removal of microorganisms by washing with water or disinfectants plays an important part. The most frequently used liquid disinfectants for washing are chlorine solutions, iodoforms, phenol and related acids, etc.; however, solutions of soap must not be overlooked for microbial decontamination purposes.

d. Radiation

Ultraviolet radiation, X-rays, gamma-rays, high-energy electrons, protons, alpha particles, and neutrons are examples of forms of radiation capable of killing microorganisms. The most common methods currently used for the sterilization of materials (surgical supplies, laboratory supplies, packaged foods, etc.) are: (1) high-energy electrons from a particle accelerator and (2) gamma-radiation from a radioactive source. Microorganisms vary significantly in their resistance to radiation, and the dosage must be determined experimentally. Irradiation sterilization with gamma-rays or high-energy electrons is used mostly with packaged goods and food products.

In certain specific applications, germicidal ultraviolet (UV) radiation is an effective means of decontaminating air and surfaces. It is sometimes used for the treatment of water and other liquids. Used in airlocks or door barriers, UV radiation can isolate areas of differing levels of contamination within a building. It is also useful for reducing extraneous contamination in rooms. Window-type air conditioners used in controlled areas may be fitted with UV lamps to decontaminate recirculated air. Ultraviolet radiation has limited penetrating power and, thus, is most effective on exposed surfaces or in air. Proper concentration, contact time, and maintenance are also critical.

e. Isolation

Isolation of a part or device in a biologically clean area will allow many organisms to die off and reduce the population. This is often an effective technique for decontamination; however, it is necessary that the food supply or energy source for organisms be eliminated. Any nutrient ability of the part or device will prevent an effective die-off rate and, therefore, poses a constraint on the use of this technique. Further, the natural die-off rate is normally so slow as to be of limited usefulness.

10.4 CRITERIA FOR MICROBIAL CONTROL

Any attempt to control microbiological contamination lacks significance unless the standards of control that must be achieved are defined; that is, the objective of the control endeavor must be defined in microbiological terms. In infectious disease laboratories the criterion may be to prevent the escape of pathogens (disease producing microorganisms). Water treatment systems are concerned with the elimination of pathogens. Food processing plants must render foods microbiologically safe for human consumption. In the hospital operating room certain air-hygiene practices are appropriate to prevent infection of patients. The techniques employed are directed toward control of harmful types of organism and essentially ignore other types which may or may not be attacked by the process. This is essentially a disinfection process.

On the other hand, many control operations require sterility to achieve the necessary effect. In either case, disinfection or sterility, contamination control criteria should be established in a manner to facilitate validation of control processes. If sterility is the aim, the criteria should specify what procedures are to be used in testing for

sterility, how many tests are needed to insure validation, when the tests are to be done, etc. If sterility is not the objective, the criteria should specify the maximum number and types of microorganisms allowed in an environment, in a solution, on a surface, in a component, etc., and should indicate the test methods to be used.

In the food industry and in the manufacture of biologicals, the control criteria are specified and controlled by certain regulatory agencies. In other areas of microbiological contamination control, no widely accepted criteria have been developed.

10.5 DECONTAMINATION STANDARDS FOR SPACE VEHICLES

In the particular area of lunar and interplanetary space flight, standards are being developed to control the microbial contamination on extra terrestrial vehicles. This is necessary to prevent transporting earth forms of living organisms to the other planets. If contamination were to occur, and the subject life form were to multiply, it would probably limit for all time the opportunity for scientific investigation of life forms on the moon and the planets. It is a major concern of the international scientific community that this does not happen. In our own space programs, NASA has established an Office of Interplanetary Quarantine charged with the responsibility and given the authority to prevent contaminating other planets with earth life forms. This requirement takes first precedence over other factors of the space program. It appears that this restriction will impose a requirement for sterility (probably achieved by a prelaunch heat soak) of space hardware involved in the Mars exploration and subsequent programs. Interim (temporary, subject to change) standards have already been issued for program definition purposes. Additional standards will be forthcoming from NASA to further clarify the requirements as they are defined and based on ensuing investigations.

Although there is a present requirement for sterility of interplanetary vehicles, the lunar program requirements are less severe. It is presumed that the lunar landings in the past have, to some extent, contaminated the moon's surface. As a practical matter, sterility of a manned spacecraft appears to be unattainable with today's technology.

For this reason the Apollo Program, at present, requires only decontamination. This can be accomplished with the application of existing technology, and will probably be achieved primarily by isolation of the spacecraft in a highly clean (microbially) atmosphere to allow the microbial load to die off to a relatively low level.

It is expected that the sterility requirements on the Apollo Program will not go beyond the consideration of the astronauts' food, drink, life support systems, and the on-board experiments.

10.6 FACTORS IN MICROBIOLOGICAL CONTROL

The significance of man in any system where microbiological contamination control is attempted deserves special consideration and understanding. Because man is an extremely profuse source of microorganisms, and because he can be extremely susceptible to those microbes that are pathogenic for him, inclusion of man in any system usually signals the weakest point in the contamination control effort. Unlike inanimate objects, man cannot be separated from a microbial population, and only with difficulty can he be enclosed in a ventilated garment to separate him from a controlled environment. These facts show that microbiological contamination control is simplified when man is excluded from the system and carries on his functions in relation to the system in a more or less remote manner. However, this cannot usually be achieved, and measures are employed to control microbiological contamination that include the presence of man as an inherent part of the system.

It is important to emphasize that potentials for microbial contamination can exist from man and other sources and yet not be detectable readily. The contamination may be present yet be odorless, tasteless, and invisible but not necessarily harmless. Moreover, instantaneous monitoring devices for microorganisms, comparable with devices for detecting radioactive contaminants, are not yet available. Next, it is important to understand the ease with which microorganisms can be made airborne, and their ability to remain airborne and to move from place to place in air currents. Finally, it is significant that the physical state of a microbiological contaminant determines the ease or difficulty of containment. Thus, dried, micronized, or powdered, microbial preparations are much more difficult to contain than contaminants in a wet or fluid state.

Even in the presence of adequate facilities and good containment equipment, the success of most attempts to control microbiological contamination depends in no small part on the work or handling techniques employed by the involved personnel. Although no inclusive list of correct techniques would be appropriate for all areas of application of microbiological contamination control, fundamentals and some general rules must be considered.

In general, "correct techniques" relate to the movements of people in the working environment insofar as these movements can minimize the spread of contamination through the air or on surfaces. These techniques, moreover, relate principally to the movement of the hands in carrying out work. An analogy can be made to the techniques of the surgeon and surgical nurse who must at all times be aware of how materials are to be handled aseptically.

How materials are handled and the proper sequence of handling are important in controlling contamination. Processes that involve violent movements, aspiration of fluids, spraying of materials, foaming or bubbling of liquids, and overflow or leakage of materials signal the need for specifying exactly how the process is to be carried out to achieve minimum spread of microbial contamination.

10.7 MICROBIOLOGICAL CONTROL FACILITIES

Modern construction criteria applied in the construction of facilities can do much to control microbial contamination. Some of the features that have been suggested for inclusion in new or renovated facilities to control contamination are:

a. Use of ventilated cabinets, chambers, cages, etc., to achieve an absolute or partial barrier to contain microorganisms at their point of use or to exclude them from a specific work area.
b. Use of clean rooms to exclude microorganisms from a particular environment.
c. Use of differential air pressures within a facility so that air moves from clean areas toward areas of higher microbial contamination.
d. Use of appropriately effective microbiological filtration of air supplied to and/or exhausted from rooms, cabinets, chambers, cages, etc.
e. Change rooms, water shower rooms, or air shower rooms for personnel.
f. Use of ultraviolet airlocks and door barriers to separate areas of unequal risk.
g. Treatment of microbiologically contaminated liquid effluents.
h. Room arrangement or layout to achieve traffic control within the facility to separate areas of unequal hazard.
i. Use of an effective communication system to avoid unnecessary movement of personnel from area to area.

The similarity between conventional contamination control facilities and microbiological contamination control is apparent (see Sections 5 and 6).

The most important major decisions in selecting features for microbiological contamination control facilities should be based on the fact that control should begin at the work surface or area where the contamination originates or where the item to be protected is located.

10.8 ISOLATION AND CONTAINMENT EQUIPMENT

Experimental evidence and practical experience have shown that handling techniques alone cannot be depended upon for consistent control of microbiological contamination. As the criteria for control become more exacting, aseptic handling techniques fail to provide sufficient containment. Facility developments, however, have provided devices that provide efficient microbiological and physical separation between environments. The most important type of containment and isolation equipment and the type capable of meeting the most severe control criteria is the gas-tight, absolute barrier enclosure. Other types such as cabinets and enclosures have been designed for the partial barrier concept wherein microbiological contamination control is achieved by controlling the direction of the air flow in or out of the critical area. Some laminar flow cabinets or benches perform in this manner.

An important aspect with regard to containment equipment is the selection of the proper type of equipment in relation to the type of contamination control or the criteria for control. According to the containment requirement, various performance standards can be established for containment equipment. Such requirements relate to (1) leak tests for the enclosure, (2) ventilation rates, (3) filtration or incineration of air supplies or exhausts, and (4) provisions for decontaminating or sterilizing the interior of the enclosure and the air filters.

10.9 MONITORING AND ASSESSING BIOLOGICAL CONTROL

In any contamination control endeavor, it is necessary to assess whether the control techniques which have been employed are effective in achieving the standards or criteria that were established. The following are the commonly used techniques to test and assess the effectiveness of biological contamination control practices.

a. *Air Sampling

Air sampling test and surveillance procedures provide data on the presence of viable airborne microbes. According to the sampling devices used, assessment can be based on microorganisms per unit volume of air, or on microorganism-containing particles per unit volume of air. Settling plates can provide data on viable organisms falling on a unit area of surface per unit of time (e.g., individuals per square foot per hour). Other types of samplers can provide estimates of the particle sizes of viable airborne particles.

The use of selective culture media in air samplers may provide an opportunity to test for specific types of microorganisms. Also, microorganisms obtained from the air during sampling can be subjected to further testing for specific identification.

b. Surface and Component Sampling

Moistened cotton swabs or Rodac plates (a test dish containing a gelatinous nutrient substance) are usually used to detect microbiological surface contamination. The Rodac plate test is performed by pressing the plate against the surface and allowing cultures to form on the plate. The swab test is performed by washing an area with a sterile solution on a cotton swab and returning the swab to the solution which allows assaying of the solution for viable organisms. Sterile test or sample strips of various material are used to collect representative samples of the accumulation of microorganisms on surfaces over periods of time.

Small components may be tested by complete immersion in an appropriate nutrient fluid or by washing the component in a sterile fluid that is assayed for viable microorganisms. These tests must be done in a sterile environment. Special microbial detection and assay tests may be devised for other materials such as oils, greases, powders, etc.

*A summary of air sampling techniques most often used was prepared by Wolf, H.W., et al, Sampling Microbiological Aerosols, Public Health Monograph No. 60, U.S. Public Health Service.

c. Physical and Chemical Tests and Measurements

According to the nature of the microbiological contamination control endeavor, a number of physical and chemical tests and measurements may be done. In some instances these tests are critical to the surveillance program and in other instances they merely provide evidence that the control criteria are being met. For instance, when wet heat is used for the sterilizing procedure, a record of the temperature, pressure, and treatment time must be recorded to insure that treatment time is maintained; when liquid or gaseous decontaminants are used these should be periodically assayed chemically to assure proper chemical concentration and pH level.

d. Testing of Filters, Incinerators, Sewage, and Water

Whenever microbial air filters, air or solid waste incinerators, or sewage or water treatment systems are a part of a contamination control procedure, these systems must be tested to assure adequacy of operation. It is particularly important to test systems prior to their being put into routine operation. In some instances microbiological tests with tracer microorganisms will be appropriate and in other instances temperature measurements and other tests are applicable. Testing must be done in such a manner that a break of sterility or containment is not involved.

e. Freon Leakage Testing

Freon testing can be used to validate the microbiological tightness of any absolute barrier system. Inability to leak molecules of freon gas is equated with the inability of microbes to enter or escape from the barrier. In a typical test for a cabinet or similar enclosure 1 ounce of freon gas is admitted for each 30 cubic feet of space. Using compressed air or an inert gas, the pressure is raised to 6 inches water gauge. At this point, if there is no leakage when tested with a Halogen Leak Detector operating on high sensitivity range, the enclosure may be considered secure.

10.10 CHECKLIST FOR MICROBIOLOGICAL CONTAMINATION PROGRAM

Table 10-1 contains a checklist or guidelines for planning a biological contamination control program.

Table 10-1

Stages, Approaches, and Techniques of Microbiological Contamination Control*

Stage 1 - Recognize and Define the Problem

Stage 2 - Establish Contamination Control Criteria

Maximum number of organisms allowed, types of organisms, where located, how detected, and other criteria.

Stage 3 - Employ Approaches and Techniques of Control

Facility Design Features	Use of Containment Equipment	Management Functions	Use of Correct Techniques	Use of Sterilizing Agents, Germicides, and Other Control Measures

Stage 4 - Microbiological Testing and Surveillance

Air Sampling	Surface and Component Sampling	Physical and Chemical Tests and Measurements	Testing of Filters, Incinerators, Sewage, Water	Freon Leakage Testing

Stage 5 - Analysis of Results and Certification Procedures

Recording results, statistical tests, use tests of items, formal or informal certification.

*This table was taken from Phillips, G.B., et al, 1965, Microbiological Contamination Control, A State of the Art Report, American Association for Contamination Control.

SECTION 11

QUALITY CONTROL

SECTION 11

QUALITY CONTROL

The quality control responsibility in a contamination control program must follow the philosophy of a beginning-to-end effort. A detailed quality control procedure is necessary to assure that all the elements for contamination control are implemented and that the effort is maintained and disciplined.

The following procedures for the certification of cleanliness of materials, personnel training, and controlled environment facilities are included here as a quality control plan for implementing and maintaining the contamination control effort. The procedures contain the elements necessary to assure an effective program.

These procedures may be used for a total quality control requirement or they may be changed or abbreviated to serve a particular need. In any case, they may be used as a guide for developing a particular quality control plan.

PART A

CONTAMINATION CONTROL

CERTIFICATION PROCEDURE

1.0 GENERAL

1.1 These procedures are intended for use by NASA and NASA contractors as the means by which an effective contamination control program will be implemented.

1.2 These procedures do not dictate the level or degree of contamination control required but present the basic elements that are essential to assure a successful program.

1.3 The contamination control plan must reflect the design intent of the article under consideration. The level of cleanliness and sensitivity to environmental conditions are determined at the design phase and are to be prescribed by design drawings and specifications. The contamination control program is then developed to achieve and maintain the prescribed limits.

1.4 Carefully reasoned judgment should be used in specifying a contamination control requirement. An excessive or unrealistic requirement for higher orders of cleanliness and environmental control than necessary will tend to destroy confidence in the general practice of contamination control and will add unnecessary delays and high costs to a program.

2.0 CONTAMINATION DEFINED

2.1 Contamination control encompasses all the measures and techniques necessary to achieve a desired level of cleanliness or freedom from foreign material

2.2 Contamination as a general term is the opposite of cleanliness.

2.3 Contamination is the presence of any unwanted foreign material referenced against absolute purity. These materials can be ordinary dirt, corrosion products, oxides, industrial dust, spores, fibres, pollen, chemical products,

or any organic or inorganic matter which adheres to, comes to rest on, or diffuses into the reference material, part, or medium.

2.4 Not all contamination is harmful.

2.5 Some degree or level of contamination is always present but can be controlled or managed at a required level.

3.0 APPLICABILITY

3.1 This procedure is applicable to NASA contracts, subcontracts, purchase orders, and NASA "in-house" activities as determined by the contracting authority.

3.2 In the event of conflict between this procedure and a drawing or specification requirement imposed by the contracting authority, the drawing or specification requirements shall take precedence and govern.

PART B

CERTIFICATION PROCEDURE

FOR THE

CLEANLINESS OF MATERIALS

1.0 SCOPE

1.1 This procedure establishes the requirement for special cleaning, handling, packaging, and care of critical, contamination sensitive components, assemblies, systems, and associated materials for use on NASA space programs.

1.2 This procedure does not establish cleanliness (contamination) levels.

1.3 This procedure defines the methods, materials, requirements, and quality control provisions necessary to assure that the prescribed cleanliness has been achieved, that cleanliness has been maintained, and that any violation of cleanliness is indicated.

2.0 PURPOSE

2.1 Cleanliness of materials is essential to achieve the high reliability required by NASA's space programs.

2.2 This procedure provides a common basis to assure achievement and maintenance of effective cleanliness of articles used within NASA organizations and by NASA contractors.

3.0 CERTIFICATION

3.1 Demonstrated compliance to the requirements of this procedure will permit certification of the prescribed cleanliness level of the subjected item(s) or material(s).

4.0 MATERIALS

4.1 Packaging material may be film, bags, boxes, cans, bottles, vials, tanks, or other material(s) suitable for the application that meets the following conditions:

4.1.1 Cleanliness of the packaging material can be determined and verified by an approved method.

4.1.2 The critical surface, i.e., the surface contacting the packaged item shall be non-sloughing (will not shed particles or contaminants) at a level required by the cleanliness of the packaged item during the intended service life of the package.

4.1.3 Packaging materials shall be compatible with and provide complete protection of the critical surface(s) of the contamination sensitive item from any anticipated adverse environment or condition.

4.1.4 The packaging material(s) shall be capable of providing a sufficiently gas-tight and moisture-proof seal to maintain cleanliness throughout the service life of the package or closure.

4.1.5 The use of colored or tinted packages or closures is encouraged for identification purposes according to an established code.

4.2 Pressure sensitive tape, adhesives, sealants, etc., may be used for packaging or closure aid at the discretion of the contractor as long as it is satisfactorily demonstrated that such usage does not compromise or tend to degrade the required cleanliness of the packaged or closed item.

4.3 Stamping and marking ink shall be of a permanent or etching type which is non-sloughing and non-smearing when dry.

4.4 Tamper-proof sealing devices shall be of a design approved by a NASA designated authority.

4.5 Decalcomanias shall be of a design approved by a NASA designated authority and shall accommodate the following information:

4.5.1 Month, day, and year.

4.5.2 Cleaning specification or procedure number.

4.5.3 Level of cleanliness.

4.5.4 Shelf life or intended useful age.

4.5.5 Provision for NASA authorized stamp.

4.6 Temporary covers or containers for interim protection shall be non-sloughing to the degree required by the cleanliness of the item and shall be of a design that will give protection from environmental contaminants and handling.

5.0 REQUIREMENTS

5.1 All contamination sensitive (critical) parts or material shall be accurately cleaned according to a specification, procedure, or method developed by the contractor and approved by a NASA designated authority.

5.1.1 NASA approval of the cleaning method requires satisfactory demonstration that the method used will consistently achieve the desired level of cleanliness.

5.1.2 Verification of the cleanliness level of contamination sensitive parts of material shall be conducted according to the following schedule:

5.1.2.1 A typical sample of parts or components shall be final precision cleaned and the cleanliness verified prior to a single shift (8 hours) operation of the final precision cleaning process; that is, verification of the cleanliness level delivered by each final precision cleaning process

shall be determined at the start of each 8-hour shift of operation. This frequency may be altered upon consideration of historical data and upon approval of the NASA designated authority.

5.1.2.2 Cleanliness levels of fluids (liquids and gas) shall be determined immediately after the final precision cleaning process on a single sample basis from each batch. An acceptable alternate system is the use of continuous, "on stream" monitoring devices.

5.1.2.3 Cleanliness of major assemblies, systems, or units shall be verified immediately prior to closure or packaging before leaving a controlled environment.

5.1.2.4 Cleanliness of miscellaneous materials, solutions, containers, etc., as used for processing purposes shall be verified at the discretion of the contractor as necessary to achieve product cleanliness.

5.2 All final precision cleaning and packaging shall be done in a controlled environment that will meet or exceed the cleanliness level required to prevent degradation of the cleaned item.

5.2.1 The controlled environment shall be capable of maintaining as applicable a specified level or less of particulate matter in the atmosphere, a specified level or less of unwanted gases, a specified relative humidity and a specified temperature.

5.2.2 A controlled environment facility shall be certified according to Part D of this procedure.

5.3 All precision cleaned parts and material shall be packaged using an approved packaging of closure material (paragraph 4.1) as soon as practicable after cleaning and prior to leaving the controlled environment. The packaging or closure method shall be according to a specification developed by the contractor and approved by a NASA designated authority.

5.3.1 Items which are not packaged (or closed) immediately (2 hours or as otherwise determined) after cleaning shall remain in the controlled environment and be further protected where practical by containers, covers, etc., to exclude possible contamination and unnecessary handling.

5.3.2 Items being worked on in a more or less continuous manner while in a controlled environment shall be covered or closed during periods of inactivity.

5.3.3 Temporary containers, closures, or covers used for interim protection within controlled environments shall meet the requirements of paragraph 4.6.

5.3.4 Packaged items requiring purging, pressurization, desiccation, or evacuation shall be so identified on the package or closure.

5.3.5 When practical, packaging considerations should allow for visual inspection through the package to eliminate the need to open the package for visual inspection.

5.4 Sealed packages or closures, not of a temporary nature, of contamination sensitive items shall incorporate a tamper-proof device that will readily and visibly indicate the violation of the integrity of the package or closure. Such a tamper-proof device may consist of, but not be limited to, any of the following techniques:

5.4.1 Torque-paint may be applied to the closure in such a manner that breaking the closure will be indicated.

5.4.2 Torque-paint applied to threads of bolts/nuts on bolted or screw type closures.

5.4.3 Safety wire and lead seal may be used for plugged, capped, or bolted closures or for lid type containers.

5.4.4 Frangible (egg shell) type decalcomania or seal.

5.4.5 Tamper-proof seals such as labels, stickers, certification stamp across closure, or similar means may be used.

5.5 A certification decalcomania according to paragraph 4.5 shall be affixed to or included in each package or closure of contamination sensitive items.

5.5.1 The certification decalcomania shall be readily visible and permanently affixed to the package or closure.

5.5.2 The certification decalcomania shall not come in contact with the contamination sensitive surface of the packaged item.

5.5.3 For multiple closures on a single part or for multiple packages in an inseparable lot, a single certification decalcomania may be used as long as the quantity of closures or packages is indicated on the decalcomania.

5.5.4 The certification decalcomania shall have the following information entered in the appropriate spaces in a legible and permanent manner:

5.5.4.1 Month, day, and year clean item was packaged.

5.5.4.2 Cleaning specification or procedure number.

5.5.4.3 Level of cleanliness achieved with reference to the above (paragraph 5.5.4.2) specification.

5.5.4.4 Shelf life or intended useful age of the package or packaged item if applicable.

5.5.4.5 NASA controlled inspection stamp, i.e., the use of the stamp is either by NASA authority or delegated by NASA authority.

Note: The use of the inspection stamp constitutes evidence of certification and indicates that the cleaned item has been cleaned and packaged according to the approved specification or procedure.

5.6 All personnel involved in the cleaning, handling, inspection, testing, packaging, storing, or use of contamination sensitive material shall be certified as having been properly trained and instructed according to Part C of this procedure.

5.6.1 Certification of personnel will be evidenced by an appropriate card or certificate bearing a statement of the successful completion of an approved program.

5.7 All stocking or inventory of cleaned material requires packaging or closing according to paragraphs 5.2, 5.3, 5.4, and 5.5, prior to entering stock or inventory.

5.7.1 Store rooms or inventory areas shall be of a controlled environment to the extent that the packaged parts are protected from any condition that may adversely affect the integrity of the package, accelerate the age of the package, or subject the packaged part to frequent handling.

5.7.2 Inventory control procedures shall be implemented to insure a first-in, first-out method of using contamination sensitive items where practicable.

5.7.3 Inventory control procedures shall include surveillance of facilities and practices to assure adequate protection to stored items.

5.7.4 Inventory records shall be maintained to show stored item, duration of storage, and circumstances and conditions of storage.

5.8 All inspection performed on a cleaned part shall be done in a controlled environment area maintained at a cleanliness level at or above that required to maintain the cleanliness of the part.

5.8.1 If it is necessary to break a closure or open a package for inspection, that part or item shall be repackaged to the same condition as the original prior to leaving the inspection area.

5.8.2 Inspection requiring opening of a package or closure shall be reduced to the minimum of occurrence that is considered to be consistent with good reliability practices.

5.8.3 An inspected/tested and resealed, reclosed, or repackaged part shall be certified in the same manner as the original.

5.8.4 A log book record shall be maintained of all incidents of opening packages or closures for inspection purposes to insure traceability in the event contamination should occur. The record shall show the date, responsible person, reason for opening, the condition of reclosing, and the disposition of the article.

5.9 Precautions shall be taken to insure that clean packages or closures are properly identified and protected from damage during handling, transportation, or shipping activities. Such precautions may include but not be limited to the following devices:

5.9.1 Durable overpack.

5.9.2 Shock resistant mountings.

5.9.3 Bright colored, well marked containers, or labels, or wrapping material for warning purposes.

5.9.4 Specially made or adapted containers, tote boxes, trays, etc., to provide protection and convenience of handling.

5.9.5 Specially built or adapted transportation vehicles to offer suitable protection to the subject item.

5.9.6 Written instructions posted in an obvious position directing special handling, storage, shipping, etc.

6.0 QUALITY CONTROL PROVISIONS

6.1 Items that are closed or sealed and bear a certification decalcomania and fulfill the intent of this procedure shall not be opened except for the end use or as required for inspection as provided in paragraph 5.8.

6.2 Quality control organizations shall insure that the intent of this procedure is fulfilled.

6.3 Quality control shall assure the cleanliness of the item, the integrity of the package, and that certification has been accomplished prior to shipment or transfer of the responsibility for the item.

6.4 Immediately prior to, or during, the installation or use of the cleaned item, quality control shall witness the destruction of the certification decalcomania. An appropriate log book entry shall be maintained of the circumstances.

6.5 The following criteria is cause for (but not limited to) rejection of contamination sensitive items.

6.5.1 Certification decalcomania missing, broken, incomplete entries, illegible, or not approved.

6.5.2 Tamper-proof seal broken, damaged, or incorrectly applied.

6.5.3 Improper seal, open seal or closure, lifted tape, etc.

6.5.4 Apparently damaged (including pin holes) or violated package or closure.

6.5.5 Visible entrapped moisture or other unwanted material.

6.5.6 Any apparent defect that may interfere with the proper function of the item.

6.6 Rework in the form of recleaning and repackaging is permitted prior to using an item that was rejected as contaminated or possibly contaminated as long as the recleaned item can meet the cleanliness level prescribed by specification or drawing and as long as certification can be applied consistent with this procedure.

PART C

CERTIFICATION PROCEDURE

FOR PERSONNEL

1.0 SCOPE

1.1 This procedure establishes the requirement for special instruction and training of all persons who handle, assemble, inspect, or engage in an activity that will bring them in direct contact with contamination sensitive components, assemblies, systems and associated materials for use on NASA space programs.

1.2 This procedure outlines the minimum requirements of an effective training program and includes the basis for selection, qualifying, and certification of personnel.

2.0 PURPOSE

2.1 In order to achieve and maintain a high degree of cleanliness and contamination control, it is deemed essential that all personnel who come in contact with contamination sensitive articles are properly trained in contamination control techniques and are made fully aware of the consequences of their actions.

2.2 Proper instruction and training of personnel will tend to reduce the exorbitant cost and waste of time caused by the improper application of contamination control techniques.

3.0 CERTIFICATION

3.1 Qualification of personnel for certification requires that each person has successfully completed a NASA approved training program meeting the requirements of this procedure.

3.2 Certification shall be evidenced by a formal card or certificate issued and controlled by the responsible quality control organization and bearing the counter-signature of an authorized NASA representative.

3.3 Continuous or repeated demonstration of proficiency will permit continuous certification.

4.0 SELECTION OF PERSONNEL

4.1 Personnel shall be chosen to work in contamination sensitive activities primarily for their ability to perform a required operation, process, or sequence. Depending upon the degree of contamination control required by a particular item, the following considerations shall be made in choosing personnel for various assignments.

4.1.1 Personnel selected for training to work in controlled environment facilities where high orders of cleanliness are required shall meet the following:

4.1.1.1 Non-allergic to conditions, materials, or solutions used in the controlled environment.

4.1.1.2 Psychologically suited for the environment, that is, no evidence of claustrophobia, nervous conditions, etc.

4.1.1.3 Willingness to follow rigid rules for dress, behavior, personal hygiene, etc., required by the degree of contamination control.

4.1.1.4 No physical disorders that tend to raise the contamination level above established normal levels such as excess skin flaking, dandruff, nasal discharge, etc.

4.1.1.5 Ability and willingness to follow specifications and procedures without deviation or substitution.

4.1.2 Personnel failing to meet the requirements of paragraph 4.1.1 should not be ruled ineligible to work with contamination sensitive articles outside controlled environment facilities so long as their activity in the area to which they are assigned does not endanger the cleanliness of the article and they are properly trained to the requirements of this procedure.

4.1.3 All personnel selected to work in an activity that will bring them in contact with contamination sensitive articles shall be capable of successfully completing the qualifying training program outlined in this procedure.

5.0 TRAINING

5.1 A minimum course of instruction for all personnel whose activities may bring them in contact with contamination sensitive articles shall contain the following elements and shall be approved by an authorized NASA representative:

5.1.1 Definition of terms associated with contamination control.

5.1.2 A presentation of the need for contamination control and the consequences of contamination. Note: The use of examples is encouraged.

5.1.3 A discussion of the origin and types of contamination including internal sources created by manufacturing or handling activities, external sources present in the prevailing environment, and personnel created contaminants.

5.1.4 A presentation of the devices and techniques used to achieve and control cleanliness including applications and limitations.

5.1.4.1 Various classes of controlled environments and cleanrooms.

5.1.4.2 Clean work stations.

5.1.4.3 Apparel and laundering.

5.1.4.4 Clean packaging.

5.1.4.5 Precision cleaning methods and materials (high purity low residue solvents, ultrasonic cleaning, etc.).

5.1.4.6 Tamper-proof seals on clean closures.

5.1.4.7 Methods of measuring and verifying contamination levels:

5.1.4.7.1 Air sampling/filtering/microscopic count.

5.1.4.7.2 Fluid wash/filtration/microscopic count.

5.1.4.7.3 Dissolved oils or chemical materials by weighing used and unused solvents.

5.1.4.7.4 A discussion of automatic monitoring devices is optional.

5.1.5 A presentation on the high orders of cleanliness capable of being achieved and necessary for manned space missions.

5.2 All personnel selected for assignment to activities within cleanrooms or controlled environments shall complete the course of instruction required by paragraph 5.1 and shall be given additional instruction which shall include the following elements and shall be approved by a NASA authorized representative.

5.2.1 Design criteria for clean rooms and clean work stations.

5.2.2 Personnel control and occupancy within controlled environments.

5.2.3 Considerations in the selection of furniture, fixtures, and tools that are used in clean rooms.

5.2.4 Design criteria for garments or special apparel.

5.2.5 Maintenance and janitorial considerations for clean rooms.

5.3 Training or instruction may be performed by responsible supervision, a designated instructor, experienced employees, or outside contractors as approved by NASA authorized representative.

5.4 The use of training aids are useful and are encouraged in developing a training program.

a. Photographs, displays, charts, etc.

b. Guided tours of typical operations.

c. Various publications and specifications.

d. This certification procedure in total.

6.0 QUALIFICATION

6.1 Upon completion of each course of instruction (paragraphs 5.1 and 5.2) the trainee shall be tested with written, basic questions on each element of instruction. A grade that indicates adequate retention and understanding of the subject must be attained to qualify for working in contamination sensitive activities.

6.2 The written test of paragraph 6.1 shall be approved by the authorized NASA representative and shall be administered by the responsible quality control activity.

6.3 The responsible quality control activity shall maintain a file of all qualifying tests.

6.4 A certificate indicating completion of the prescribed training shall be prepared for each successful trainee by the quality control organization. A counter-signature by the NASA designated authority completes certification.

PART D

CERTIFICATION PROCEDURE FOR

CONTROLLED ENVIRONMENTS

1.0 SCOPE

1.1 This procedure establishes the requirement for testing, monitoring and maintaining the design and operational functions of controlled environment facilities and operations used in the manufacture, inspection, test, and handling of articles for NASA space programs.

1.2 This procedure does not establish degrees of cleanliness or environmental levels of humidity, temperature, etc. The degree and level of control is a function of the product requirements as defined by product specification.

1.3 This procedure presents the methods and provisions necessary to assure that the required cleanliness and environment has been achieved and is maintained.

2.0 CONTROLLED ENVIRONMENT FACILITY DEFINED

2.1 A controlled environment facility is a device or accumulation of devices which will contain and isolate an activity from external influences and will control internal conditions so as to achieve and maintain a desired environment.

2.2 A controlled environment may be accomplished by the use of specially designed work stations, contained rooms, isolation areas, or the control of entire building structures. They may consist of permanent facilities, temporary rooms, portable, movable confinements, or other devices to create and control the desired conditions.

3.0 PURPOSE

3.1 Controlled environment facilities are necessary to achieve the high levels of cleanliness and environmental control as specified for articles used for NASA space programs.

3.2 Proper application and use of controlled environment facilities will tend to minimize cost and will contribute to efficient manufacturing and test programs.

3.3 This procedure will provide a common basis upon which to institute the measures necessary to insure the proper use of controlled environment facilities.

4.0 CERTIFICATION

4.1 For purposes of this procedure, certification is defined as the acknowledgment by the contracting authority that the controlled environment facility is capable of achieving the specified conditions and has satisfactorily demonstrated this capability.

4.2 Certification shall be evidenced by the issuing of a formal statement by the NASA designated authority that the controlled environment facility is demonstrated to meet this procedure.

4.3 Continuous or repeated demonstration of meeting this procedure will permit continuous certification.

5.0 REQUIREMENTS

5.1 The controlled environment facility shall be capable of achieving and maintaining that level of environmental control and cleanliness prescribed for the handling, assembly, inspection, test, or storage of the subjected item.

5.2 DESIGN CRITERIA

5.2.1 The facility shall be designed to exclude external influences such as airborne particles, humidity, temperature, etc., to the extent required to maintain the integrity of the subject items. Measures taken shall include but not be limited to the following:

5.2.1.1 The confined activity shall maintain a positive internal atmosphere pressure differential as necessary to

positively exclude the entry of the external atmosphere.

5.2.1.2 The make up air or atmosphere entering the confined activity shall be filtered, cleaned, scrubbed, or otherwise treated to the extent required to achieve and maintain the required cleanliness and environmental conditions.

5.2.1.3 The use of air locks and pass throughs shall be included and constructed as applicable to minimize the violation of the positive pressure differential.

5.2.1.4 Movement of personnel, parts, materials, supplies from an area into an area designated at a higher degree of cleanliness and environmental control shall be controlled by design of the facility. Such controls may include the following devices:

5.2.1.4.1 Air showers for personnel.

5.2.1.4.2 Shoe cleaners, tacky mats.

5.2.1.4.3 Clothing change areas.

5.2.1.4.4 Cleaning equipment for parts, materials supplies.

5.2.1.4.5 Closed communication media (telephones, windows, etc.) to reduce traffic.

5.2.2 The facility shall include measures to control internal conditions as necessary to reduce degradation of the controlled environment.

5.2.2.1 Floors, walls, and ceilings shall be constructed and finished in such a manner to minimize shedding or sloughing particles, to reduce the entrapment of particles, and to present easily cleaned surfaces.

5.2.2.2 Furniture, facilities, and fixtures shall be of a design to reduce shedding or sloughing of particles, to reduce the entrapment of particles, and to present easily cleaned surfaces.

5.2.2.3 The design shall consider the work flow within a controlled environment to permit the most economical operation consistent with the required degree of environmental control and cleanliness.

5.2.2.4 Air flow patterns shall be designed to minimize the entrapment or buildup of contamination consistent with the requirement for cleanliness.

5.2.2.5 Special considerations shall be given during design for those operations that generate or create contaminants (filing, soldering, grinding, etc.), to contain or exhaust the contaminants to prevent their migration or entry into other activities.

5.3 OPERATING CRITERIA

5.3.1 The operation of a controlled environment facility places restrictions upon the work being done in that facility. These restrictions will vary according to the degree of environmental control and cleanliness required by the operation. In order to achieve economy of operation and to realize the best utilization of the facility, each operation shall be carefully considered prior to installation in a controlled environment. Every attempt shall be made to place operations within a controlled environment that will not exceed the requirements of the operation by more than reasonable tolerance or safety margin.

5.3.2 A written operating instruction shall be prepared for the operation of a controlled environment facility. The instruction shall be

approved by a NASA designated authority and shall contain, but not be limited to, the following elements:

5.3.2.1 All personnel, including visitors, shall observe a written procedure for entry into the designated or confined area. The occupancy number shall be limited during a given time.

5.3.2.2 Only work determined to be sensitive to environmental conditions or contamination and specifically scheduled for entry into the controlled environment shall enter the controlled environment.

5.3.2.3 Tools, supplies, and personal items entering the controlled environment shall be limited and controlled.

5.3.2.4 Protective clothing, if used, shall be worn according to a precise instruction and shall be changed according to a fixed schedule. Laundering, packaging, and storing of protective clothing shall be included in the instruction.

5.3.2.5 All work entering the controlled environment shall be cleaned in such a manner as to reduce the introduction of contaminants.

5.3.2.6 Routine janitorial service shall be performed either on a continuous basis or according to a fixed schedule. Detail cleaning procedures shall be prepared including cleaning methods, materials, and equipment.

5.3.3 All personnel assigned to work in the controlled environment shall be certified according to the provisions of Part C of this procedure.

5.3.4 Whenever or wherever practicable maintenance, rearrangement, or installation of new equipment shall be performed during periods of inactivity of the controlled environment, measures shall be taken

to assure that normal operations within the controlled environment are isolated and protected from any adverse effects of maintenance, rearrangement, or installation. Preventive maintenance shall be practiced to the extent deemed practical.

5.4 MONITORING THE CONTROLLED ENVIRONMENT

5.4.1 Continuous or scheduled monitoring shall be conducted of all primary conditions controlled within the controlled environment. Such monitoring may include particulate contamination of the atmosphere, biological contamination, gaseous contamination, humidity, temperature, or any other element of environment that is controlled and may affect the subjected articles.

5.4.2 A written procedure for sampling, testing, or monitoring the controlled environment shall be prepared. The procedure shall be based on data derived from the operation of the controlled environment under normal or simulated operation conditions. The data used to develop the procedure shall be representative of all elements to be controlled. The written procedure and the data upon which the procedure was based shall be approved by the NASA designated authority prior to certification of the facility.

Note: Operations may be performed within the controlled environment during the collection and preparation of data to develop the monitoring plan, providing all other conditions of this procedure have been fulfilled, at discretion of the NASA designated authority.

5.4.3 The written procedure (paragraph 5.4.2) shall contain but not be limited to the following elements:

5.4.3.1 The environmental condition(s) to be monitored.

5.4.3.2 The detailed method of monitoring (continuous or sample).

5.4.3.3 The equipment used.

5.4.3.4 Frequency of monitoring and location(s) of sample(s) or sensor(s).

5.4.3.5 Reference to appropriate specifications and standards.

5.4.3.6 Precautions or details to assure good operating practice for monitoring personnel (special clothing, entry procedures, sample care, etc.) shall be presented.

5.4.4 The quality control organization shall maintain a daily log of the environmental condition being monitored showing a plot of the measured parameter compared to the required (desired) level of control. The log will, in addition, record periods of inactivity, shutdown, out of control conditions, or unusual activity.

5.4.5 All controlled environments shall be monitored a minimum of once per day during a period of operation (not during start up, lunch period, break periods, or other than normal activity). Beyond this minimum requirement the frequency and schedule for monitoring shall depend on the developed data (paragraph 5.4.2).

5.4.6 Personnel conducting the monitoring activity shall belong to the quality control organization. These personnel shall be trained and certified according to Part C of this procedure and, in addition, shall be carefully instructed in the monitoring techniques to be used. Personnel performing the monitoring shall demonstrate proficiency to the satisfaction of the NASA designated authority. Where practical, personnel shall be compared one to the other and/or against previously prepared standards, in order to assure continued proficiency.

5.4.7 Preparation of samples and analysis shall be conducted in a controlled environment. The selected laboratory area or location shall have those elements of environment controlled to a higher degree than the operational environment and shall be monitored and recorded a minimum of once per day.

5.4.8 Calibration of equipment used in monitoring shall be performed consistent with quality control practices.

SECTION 12

REFERENCE SPECIFICATIONS, STANDARDS, AND PROCEDURES

SECTION 12

REFERENCE SPECIFICATIONS, STANDARDS, AND PROCEDURES

This section was prepared for use by design and operations personnel who are concerned with contamination of their products. It is intended to create a state-of-the-art reference file of contamination control and cleanliness standards. An attempt was made to compile and abstract as many as possible of the authoritative specifications, standards, and procedures pertinent to the subject. A comparison chart (Table 12-1) was prepared to indicate the relative coverage of the various subjects. Also, in subsequent pages a brief review of each entry was made so that its usefulness can be easily ascertained.

Although many specifications from industry were considered, most of them were not included in this section because they were prepared primarily to meet the requirements of Government specifications and consequently were redundant. The specifications and procedures that are included are believed to present the extent of present established techniques and specification coverage in contamination control pertinent to manufacturing, testing, and installation of Apollo space hardware.

Many subjects are not thoroughly covered or evaluated by present specifications. Much work needs to be done by both industry and Government agencies to develop better specifications in such areas as biological sterilization, packaging, automatic monitoring, certification procedures, and other areas. As new specifications are prepared, they will be added to this reference file.

The reference numbers listed in the left-hand column of Table 12-1, as well as the reference numbers mentioned throughout the handbook, correspond to the reference numbers assigned to the documents reviewed in this section.

Table 12-1

Comparison Chart of Specifications, Standards, and Proc

Code:
1 - Obsolete - Useful for Reference Only
2 - Briefly Mentions Subject - Limited Usefulness
3 - Covers Subject - Not Adequate by Itself
4 - Covers Subject - Adequate

Reference Number	Agency and Document No.	Principal Subject	Controlled Environments Design, Operation, Maintenance: Clean Rooms, Facilities, Equipment	Portable Clean Rooms	Clean Work Stations	Apparel or Garments	Certification Facilities/Personnel		Clea: Metal Parts	Plastic Parts	Hydraulic Systems
1.	Federal FED-STD-209	Clean Room Facilities	4		3						
2.	USAF T. O. 00-25-203	Clean Room Operation	4		3	3					
3.	NASA/MSFC STD-246	Clean Room Facilities	3		2	2	2				
4.	NASA/MSFC R-ME-MPROC-190.0	Clean Room Operation Valve Clinic	3		3	4	3				
5.	NASA/KSC (No. Not Assigned)	Clean Room Design	4	3	3						
6.	NASA/MSFC (No. Not Assigned)	Portable Clean Rooms		4							
7.	USAF Rpt. No. 17.0012.04.04	Clean Room Certification					3				
8.	SAE ARP-743	Particle Count - Air									
9.	ASTM F25-63T	Particle Count - Air									
10.	NASA/MSFC QUAL-MT-3	Particle Count - Air									
11.	ASTM F51-65T	Particle Count - Apparel				3					
12.	ASTM F24-62T	Particle Count - Surfaces									
13.	NASA/MSFC PROC-151	Contamination Control General Practice	2			2	2				2
14.	NASA/H'qts. (No. Not Assigned)	Operation of Bio-Clean Facilities	3			3	2				
15.	NASA/MSFC Dwg. No. 10MO1445	Procedure to Clean Instrument Compartments									
16.	SAE ARP-598	Particle Count - Fluid									
17.	SAE ARP-599	Particle Count - Filter Elements									
18.	USAF T. O. 42C-1-11	Operational Cleaning for Missile Systems	2						4	4	4
19.	NASA/MSFC SPEC-164	Cleanliness Level for Fuel Systems							2	2	
20.	NASA/MSFC PROC-195	Contamination Testing Using Gas									
21.	NASA/MSFC Dwg. No. 10419906	Gas Supply Systems									
22.	NASA/MSFC PROC-245	Hydrocarbon Content									
23.	NASA/MSFC PROC-166B	Hydraulic Systems, Fluids	2						3	3	4
24.	NASA/MSFC SPEC-237A	Cleaning Solvent							2	2	2
25.	USAF T. O. 42C-1-8	Rust Remover									
26.	NASA/MSFC Dwg. No. 10411901	Cleaning Bellows and Ducts									
27.	USAF T. O. 42B6-1-1	Oxygen	2								
28.	Speciality Converting Inc.	Plastic Film for Packaging									
29.	Controlled Environment, Inc.	Bibliography									
30.	NASA/MSFC Dwg. No. 60B32086	Hydraulic									1
31.	GE/RSD Mariner B	Spacecraft Sterilization	3						2	2	
32.	NASA/MSFC STD-343	Packaging									
33.	NASA/KSC KSC-C-123	Cleaning and Cleanliness Levels in Support Equip.							4	4	4
34.	DOD MIL-STD-1246	Clean Rooms and Cleaning Procedures	3	2	2	2	1		2	2	
35.	AIA Handbook	Cleaning and Cleanliness Rocket Propulsion Sys's.	3	3	3		2		4	4	
36.	SAE ARP-785	Contamination by Weight—Fluids									
37.	ASTM F50-54T	Particle Count-Air Light Scattering									
38.											

ning of Parts or Systems							Testing/Monitoring Contamination Level								
and Components	Propulsion and Fuel Systems and Components	Pneumatic Systems and Components	Breathing Gas Systems and Components	Precision Parts	Certification of Cleanliness Level		Fluids	Precision Parts	Clean Room Atmosphere	Fuel, Oxidizer, Propulsion Systems	Tanks, Lines, Vessels	Apparel or Garments		Packaging	Comments
									2						Establishes Clean Room Classification
									3			3			Most Comprehensive Specification Available
									2						Obsolete Specification Uses Old Classification System
									3			3		2	Outlines Automatic Particle Monitoring, Methods, and Equipment
															Makes Comparisons Among the Various Designs
															Handbook for Reference Use
									3						Report Only - Not a Specification - Proposed
									4						Manual Method Only
									4						Manual Method Only
									4						Manual Method Only
												4			Proposed Manual Method
								4							Small Parts Only
2														2	Procedure Only - Useful as a Reference
					2				3			2			Interim Requirement
				1	1										Cleaning Procedure Only
							4								Standard Practice Manual Method
							4								Cleanliness of Filter Elements
4	4			2	3		4	4		4	4	2		3	Most Comprehensive Specification Available
1	1						3	2		3	3			2	USAF T. O. 42C-1-11 Is More Stringent
	3						3				3				Test Procedure Via High Pressure Gas Purge Method
	3						3								Cleanliness Level for Gas Supply Systems - Surfaces
	4						3			3					Oil Content in Compressed Gases for Pneumatic Systems
				3	2		4	3						2	Comprehensive Specification on Hydraulic Systems and Fluid
	2			3				3							Quality Provisions for a Cleaning Solvent
3															Chemical Rust Remover
3														2	Gross Cleaning Procedure
2		2					2			4	4				Quality Provisions for Oxygen
							3							2	Testing Cleanliness of Film Via Wash Method
															Lists of Titles of Papers Re: Contamination Control
							3	3							MSFC-PROC 166B
					2			2	2			2		2	Bio-Clean Techniques and Guidelines
														3	General Packaging Procedure
4	4			3	3		4	3		3	4			3	Establishes Cleanliness Levels and Cleaning Procedures
				2	2				1						General Guide
4	3	2		3	3		4	4	3	4	4		3	3	Similar in Coverage to AF - T. O. 42C-1-11
							3								Testing Hydraulic Fluid Contamination
									4						Automatic Method by Light Scattering

AGENCY: Federal

NUMBER: Fed. Std. No. 209 REV: DATE: 16 December 1963

TITLE: Clean Room and Work Station Requirements, Controlled Environment

ABSTRACT: This standard defines and establishes the classes of clean environments, outlines preferred construction details, and describes the operation and maintenance of clean facilities. Monitoring techniques are briefly discussed. Individual work station construction is indicated as a method of upgrading existing facilities.

REVIEW: Fed. Std. No. 209 is generally accepted as the general specification regarding clean rooms and establishes the standard classes of clean environments. This is an information type document. It contains non-mandatory requirements and should not be used as a controlling specification. There is a bias within the document in favor of the laminar flow concept over the conventional flow that is not fully qualified. This document is considered as a guide only in clean room design, construction, and operation.

Reference No. 2

AGENCY: Air Force

NUMBER: T. O. 00-25-203 REV: DATE: 22 July 1963

TITLE: Standards and Guidelines for the Design and Operation of Clean Rooms and Clean Work Stations

ABSTRACT: This document establishes the design and operating standards for the construction, operation, and maintenance of clean rooms and clean work areas to meet the Air Force requirements for maintenance and overhaul facilities. Clean room classifications are in accordance with Federal Standard 209 and both laminar flow and conventional clean rooms are considered. The Air Force approach is to establish a large clean room and maintain it at a lower, relatively easily kept, cleanliness level and utilize individual clean work stations within the clean room to achieve higher orders of cleanliness. Employee discipline, attitudes, and training are briefly discussed. Standards are established for clean work stations. Garments and other special equipment are considered.

REVIEW: This document was designed for Air Force use at Air Force maintenance and overhaul installations. It is not for use in manufacturing activities. The document is consistent and compatible with Federal Standard 209 but is not designed for general use. Material handling, certification of operators, and personnel training are not covered in detail. The nature of particulate contamination is discussed in full. There is no special consideration given to chemical, biological, or other types of contamination.

AGENCY: NASA/MSFC

NUMBER: MSFC-STD-246 REV: DATE: 29 July 1963

TITLE: Design and Operational Criteria of Controlled Environmental Areas, Standard For

ABSTRACT: This specification establishes the design and functional criteria for controlled environment work areas. The operation and controls for standard controlled environment facilities are defined. Controlled environments are classified by four classes (in accordance with the now obsolete Air Force system). Cleanliness levels and temperature and humidity controls are established for each classification. Personnel, clothing, utilities, furniture, and fixtures are described.

REVIEW: This specification classifies controlled environments in four classes using a now obsolete classification system. The procedures and controls although effective, are based on the obsolete classification.

Reference No. 4

AGENCY: NASA/MSFC

NUMBER: R-ME-MPROC-190.0 REV: DATE: 30 March 1964

TITLE: Operation and Maintenance Procedure - Building 4705

ABSTRACT: This procedure is intended to serve as a guide for the operation of MSFC valve clinic (clean room or controlled environment area). The procedure outlines responsibility, operation, maintenance, and methods. The first section defines the operation and controls, including methods and procedures. The second section deals with the design, selection, care and laundering of clean room garments and apparel. The third section describes the furniture and fixtures that should be used. The fourth section describes the requirements for the selection of personnel to work in this area. The fifth section deals with cleaning and preventive maintenance methods and procedures for the facility. The sixth section is general information useful for training personnel and reference purposes. The appendix describes the method to use for automatic monitoring the particle count of the atmosphere using automatic particle counting equipment (Royco Model PL200A).

REVIEW: This document presents a detailed program or procedure for operation and control of a controlled environment fabrication facility. Although it was prepared to meet the specific requirements of MSFC, the requirements are similar to many other applications. This is a comprehensive, accurate, realistic procedure that has been proven in operational use.

AGENCY: NASA/KSC

NUMBER: Number not assigned. REV: DATE: 1 December 1964

TITLE: Clean Rooms - A Study by KSC Facilities Engineering and Construction Division (F)

ABSTRACT: This report is the result of a study by Kennedy Space Center (Cape Kennedy) Facilities Engineering to review the clean room facilities, of both the Government and contractors, in use at KSC. The physical facilities in operation at KSC are described. The clean rooms (24) vary widely in size, type, and use. The kind of work done in each is described. There is included a general discussion on the selection and use of the various facility designs. Advantages and disadvantages are explained. Federal Standard No. 209 and Air Force T. O. 00-25-203 are used to classify and to define terms.

REVIEW: This study is useful in describing the variety of clean room configurations and operating practices currently being used. Because both NASA and NASA contractors' clean rooms are described, the study presents a comprehensive description of the degree to which present clean room technology is being applied to space programs.

Reference No. 6

AGENCY: NASA/MSFC

NUMBER: Number not assigned REV: DATE: 1 October 1963

TITLE: Handbook of Application and Operations for Portable Clean Room System (by M-ME-P)

ABSTRACT: Space vehicle components, assemblies, systems, etc., are carefully cleaned and packaged to meet stringent cleanliness level specifications. It is an absolute requirement to maintain this cleanliness during assembly and installation to the space vehicle. Portable inflatable clean room and accessories have been conceived for this purpose. This booklet outlines several applications of this equipment, its set up, use, and maintenance.

REVIEW: This is a reference document intended to explain and present basic information on the design and use of portable clean rooms. The application of this concept is dependent on the imagination and creativity of the various using agencies.

AGENCY: Air Force/Headquarters MAAMA, Olmsted AFB, Pa.

NUMBER: Reports Control Symbol REV: DATE: 3 April 1964
17.0012.04.04

TITLE: Clean Room Certification

ABSTRACT: This document is a report which proposes a system or procedure to certify clean rooms from both the design and operational standpoint. This report points out the need for certification and the problems involved. Two types of certification are proposed: (1) primary certification to take place initially and on a yearly basis and (2) secondary certification to take place monthly (suggested period). The certification does not take the place of monitoring or test practices but develops a basis from which to measure deviations.

REVIEW: This document is a report only offering a proposed method of certification. The case for certification is well established and the proposed method is realistic; however, the proposal would require further refinement for a particular application. Certification of personnel is not discussed. This plan is for operating facilities.

Reference No. 8

AGENCY: Society of Automotive Engineers/Aerospace Recommended Practice

NUMBER: ARP-743 REV: DATE: 30 August 1962

TITLE: Procedure for the Determination of Particulate Contamination of Air in Dust Controlled Spaces by the Particle Count Method

ABSTRACT: This document describes a procedure for determining the particulate contaminants 5 microns or larger in the air. The method described is to draw air from the controlled area using a vacuum pump. The air is drawn through a filter disc upon which the entrained contamination is accumulated. A volumetric flow meter is used in the system to accurately determine the volume of sample air. The filter disc is examined microscopically to determine, by counting, the amount and size range of contaminants.

REVIEW: The method described should be expected to be ±33 percent accurate in successive tests. The method described is considered the standard, most universally used for manually determining particulate contamination levels. Although this method is time consuming (reported to require about 20 minutes to take the sample and 30 minutes to prepare and read the sample), it has the advantage of low equipment cost and of allowing the identification of contaminants as compared to automatic equipment. This method is not considered accurate for particles below 5 microns. This procedure is the same as American Society for Testing and Materials Procedure ASTM-F25-63T.

AGENCY: American Society for Testing and Materials

NUMBER: ASTM-F25-63T REV: DATE:

TITLE: Sizing and Counting Airborne Particulate Contamination in Clean Rooms and Other Dust-Controlled Areas Designed for Electronic and Similar Applications

ABSTRACT: This document presents a procedure for counting and sizing airborne particulate matter 5 microns and larger. The method described is to use a vacuum device to pass sample air through a membrane filter. The particles impinged upon the filter are sized and counted by the use of a microscope. No distinction is made between particles and fibres. The appendix outlines a method of sampling a moving gas (within a duct) and a typical monitoring system for a manufacturing area.

REVIEW: The method described is the same as SAE specification ARP-743 and the specifications are equivalent. This method is considered to be the standard method for manually determining the particulate contamination level of a controlled environment. Note this method is not considered adequate to determine particulate contamination below 5 microns. (Refer to SAE-ARP-743).

Reference No. 10

AGENCY: NASA/MSFC

NUMBER: QUAL-MT-3 REV: DATE: 21 August 1962

TITLE: Procedure for the Determination of Particulate Contamination of Clean Room Atmosphere by the Particle Count Method

ABSTRACT: This procedure describes a method to determine particulate contamination 5 microns and larger in a clean room atmosphere. The method described is the same as ASTM-F25-63T and SAE-ARP-743. This method uses a vacuum to draw sample air from the clean room through a filter disc. The filter disc is examined microscopically to count and size the accumulated particles.

REVIEW: The method described is considered the standard method for manually determining particulate contamination of clean room atmosphere. Cleanliness levels are not established. This is a procedure only. The clean room classifications used are in accordance with an obsolete system.

AGENCY: American Society for Testing and Materials

NUMBER: ASTM-F51-65T REV: DATE: 1 April 1964

TITLE: Tentative Method for Sizing and Counting Particulate Contaminant in and on Clean Room Garments

ABSTRACT: This method defines a procedure to be used for determining the particulate contamination 5 microns and larger, on or in the fabric of clean room garments. The method uses a vacuum to draw air through designated areas of a single thickness of garment fabric at a determined rate. The air passes through a filter disc impinging entrained particles upon the filter. The filter disc is examined microscopically to count and size particles. The method is designed to be similar to ASTM-F25-63T (counting particulate contamination in clean room air) to minimize equipment and skills. A proposed classification level for various degrees of garment cleanliness is presented.

REVIEW: The method is consistent with and can be used in conjunction with the standard methods for manually counting contamination levels in clean room atmosphere (ASTM-F25-63T and SAE-ARP-743). This is a procedure only, cleanliness levels are not established.

Reference No. 12

AGENCY: American Society for Testing and Materials

NUMBER: ASTM-F24-62T REV: DATE: August 1964

TITLE: Tentative Method for Measuring and Counting Particulate Contamination on Surfaces

ABSTRACT: This standard described the procedure for determining the size and distribution of particulate contamination 5 microns or larger either on, or washed from, the surface of small devices or components. Two procedures are described: one for adhered particles on planar surfaces; the second is for particles removed from irregular surfaces. The same technique for microscopic examination and sizing is employed for either procedure. For planar surfaces the part is mounted on the microscope stage for direct examination; for irregular surface parts, the parts are immersed in water/detergent and subjected to ultrasonic cavitation. The water is filtered and the filter disc is examined microscopically.

REVIEW: This is considered the standard method for determining particulate contamination of small parts. Another version of this method using solvent rather than water/detergent is often used and is generally accepted as consistent with this specification. A fibre is defined as "particles longer than 100 microns with a length-to-width ratio of greater than 10:1." This definition will vary in other specifications (AF T. O. 42C-1-11). This is a procedure only. Cleanliness levels are not established. This method is not considered accurate to determine particulate contamination count for particles smaller than 5 microns.

AGENCY: NASA/MSFC

NUMBER: MSFC-PROC-151 REV: DATE: 29 March 1963

TITLE: Contamination Control and Environmental Protection of Space Launch Vehicles and Associated Equipment, Procedure For

ABSTRACT: This document specifies the methods to be used for contamination control and environmental protection of space launch vehicle components and associated equipment through prelaunch operations. This includes receiving, maintaining, shipping, and storing operations.

REVIEW: This specification does not establish cleanliness levels or requirements but presents the general procedures to use to maintain cleanliness when the cleanliness level is specified by the responsible agency. This is considered a minimum specification outlining only the general practices that should be employed. There are no certification requirements nor any provisions to assure compliance.

Reference No. 14

AGENCY: NASA/Headquarters

NUMBER: Number not assigned REV: DATE:

TITLE: Draft: Interim Requirements For Bioclean Facilities
(Prepared for review and revision)

ABSTRACT: This document defines the design, operation, and facilities required for the manufacture, assembly, testing, and launch of spacecraft required to be biologically decontaminated or sterilized before flight. Specific requirements are established such as personnel control, maintenance procedure, method of sampling, and analysis. Controls and biocontamination levels are established.

REVIEW: This document is intended for interim use until an improved document can be prepared. This is considered to be the best presentation on bioclean considerations for space applications that is available. The levels and procedures established are subject to revision on the basis of continuing research.

AGENCY: NASA/MSFC

NUMBER: MSFC Dwg. No. 10M01445 REV: DATE: 23 May 1961

TITLE: Cleaning of Pressurized and Nonpressurized Instrument Compartments, Procedure For

ABSTRACT: This document establishes the need and the responsibility for contamination control procedures within instrument compartments of space vehicles. Methods and procedures are not described, cleanliness levels are not established, and test methods and requirements are not included.

REVIEW: This drawing stipulates the need for contamination control and the organizational responsibility. Means of accomplishment are not included.

Reference No. 16

AGENCY: Society of Automotive Engineers/Aerospace Recommended Practice

NUMBER: ARP 598 REV: DATE: 1 March 1960

TITLE: Procedure for the Determination of Particulate Contamination of Hydraulic Fluids by the Particle Count Method

ABSTRACT: This specification describes the test procedure for determining the particulate contamination 5 microns and larger in hydraulic fluids. The test described passes the fluids through a filter disc using a vacuum. The filter disc is examined microscopically to determine the amount of contaminant in stated size ranges.

REVIEW: The test method described is the accepted standard procedure for determining the contamination level in hydraulic fluids. This method appears as the test method prescribed in MSFC-PROC-166B specification for hydraulic components, systems, and fluids. This is a procedure only and does not establish cleanliness levels.

AGENCY: Society of Automotive Engineers

NUMBER: ARP 599 REV: DATE: 30 August 1962

TITLE: A Dynamic Test Method for Determining the Degree of Cleanliness of the Downstream Side of Filter Elements

ABSTRACT: This test method describes a procedure for determining the insoluble contamination level of the downstream side of filter elements. A representative portion of the contamination in the "as received" filter element under test is removed by subjecting the filter element to a sonic cavitational field while simultaneously passing test fluid through the filter element and into a membrane filter holder. The contamination is accumulated on the membrane filter disc which is removed and examined microscopically to determine contamination level.

REVIEW: Results of this procedure are intended to be used only for evaluation of the effectiveness of various cleaning treatments or cleanliness of filter elements as received from manufacturers. This is not intended as a method for determining contamination that may be present or released in service use.

Reference No. 18

AGENCY: USAF

NUMBER: T. O. 42C-1-11 REV: DATE: 24 April 1965

TITLE: Technical Manual, Cleanliness Standards; Cleaning and Inspection Procedures for Ballistic Missile Systems (Supersedes T. O. 42C-1-11 Dated 18 September 1962 and all Supplements Thereto)

ABSTRACT: The purpose of this technical order is to provide operational cleanliness standards, cleaning, decontamination, and inspection procedures for missile systems, components, and ground support equipment. The scope covers components and systems associated with liquid or gaseous oxygen, nitrogen, liquid, and gaseous fuel and fuel blends, other propulsion fluids and hydraulic fluids and systems. The manual applies to operations performed at facilities designated for the support of the missile systems. Cleanliness levels and cleaning procedures are established. General requirements, policies, and practices are included. Safety precautions and special handling techniques are emphasized.

REVIEW: This is a comprehensive and authoritative document on the subject of contamination control at the operational level of missile (rocket) propulsion systems and components, fuel, oxidizer, hydraulics, and related elements. The procedures and cleanliness levels defined were established through close cooperation of the Air Force with the missile industry and support contractors and are based on the total Air Force and industry experience since the advent of the first missile program to the present time.

AGENCY: NASA/MSFC

NUMBER: MSFC-SPEC-164 REV: 14 DATE: 27 July 1964

TITLE: Cleanliness of Components for Use in Oxygen, Fuel, and Pneumatic Systems

ABSTRACT: This specification establishes the cleanliness levels and the inspection/test procedures to confirm the cleanliness of components used in oxygen, fuel, and pneumatic systems of space vehicles and associated equipment. The cleanliness levels and test procedures cover material types as follows: rigid tubing, flexible hose, control assemblies, metallic containers, and miscellaneous metallic and non-metallic parts and components. The cleanliness level is stated as allowable particle count and nonvolatile residue concentration. The test is performed by way of a solvent wash method. The solvent is filtered and microscopic examination of the filter reveals the entrained particles for counting and sizing. Nonvolatile residue is determined by the difference in weight of the residue from used and unused solvent.

REVIEW: The particulate contamination level permitted by this specification is: (1) no particles greater than 2500 microns; (2) one particle between 700 and 2500 microns; (3) five particles between 175 and 700 microns. There is no stipulation for particles smaller than 175 microns and no distinction is made for fibres. This contamination level is the same as the level established earlier by the Air Force for the Thor Missile. Since that time the Air Force has worked closely with the manufacturers of missiles, booster engines, cryogenic manufacturers, fuel manufacturers, and many others to establish cleanliness levels for oxygen, fuel, and pneumatic systems that can be realistically maintained to assure high performance requirements. The revised cleanliness levels prepared by the Air Force and the methods of achieving and maintaining these cleanliness levels are, in general, more stringent than those outlined in MSFC-SPEC-164. The specification which presents the Air Force requirements and procedures is T. O. 42C-1-11 (the latest revision to be released 24 April 1965).

Reference No. 20

AGENCY: NASA/MSFC

NUMBER: MSFC-PROC-195 REV: 1 DATE: 30 September 1963

TITLE: Cleanliness Level Requirements and Inspection Methods for Determining Cleanliness Level of Gas Bearing Gas Supply and Slosh Measuring Systems, Procedure For

Note: Slosh measuring systems were formerly called helium supply systems.

ABSTRACT: This specification establishes the cleanliness level and the method for testing (1) gas bearing gas supply systems and (2) slosh measuring systems. The method of measuring requires that a clean compressed gas be passed through the part and then through a filter which accumulates any particulate matter picked up by the gas. Then the filter is examined and a particle count is made by use of a microscope. The test gas is trapped and a condensable hydrocarbon test is made by the scrubber method (MSFC Dwg. No. A10419962).

REVIEW: This specification establishes the method for testing cleanliness levels using compressed gas as the test medium. This technique has application for items other than gas bearing supply and slosh measuring systems. Refer to MSFC Dwg. No. 10419906 for cleaning and testing critical surfaces of parts that cannot be tested by way of the compressed gas method.

AGENCY: NASA/MSFC

NUMBER: Dwg. No. 10419906 REV: B DATE: 26 June 1962

TITLE: Cleanliness Levels, Cleaning and Inspection Procedures for Component Parts of Gas Bearing and Slosh Measuring Systems, Specifications For
Note: Slosh measuring systems were previously called helium supply systems.

ABSTRACT: This specification covers the cleaning and inspection procedures and the cleanliness level requirements for all metallic, polytetrafluoroethylene (TFE Teflon) and nonmetallic surfaces (other than Teflon) of disassembled component parts for gas bearing or slosh measuring systems for space vehicles or support equipment. The cleaning procedures outlined involve detergent/water wash, vapor degreasing (metallic and Teflon), demineralized water rinse to neutral Ph, and gas and/or vacuum dry. Particle count is made by solvent wash of the critical surface, filtering the solvent, and microscopic examination of the filter. Nonvolatile residue (hydrocarbon) content is determined by the difference in weight of the residue used and unused solvent.

REVIEW: This specification is designed for maintaining contamination control of surfaces. This technique has application for items other than gas bearing and slosh measuring systems. Refer to MSFC-PROC-195, which is the specification for parts and assemblies that can be cleaned and tested by the compressed gas method (tubes, fittings, filters, etc.).

Reference No. 22

AGENCY: NASA/MSFC

NUMBER: MSFC-PROC-245 REV: DATE: 23 May 1963

TITLE: Carbon Tetrachloride Scrubber Method for Analysis of Condensable Hydrocarbon Contamination in Compressed Gases, Procedure For

ABSTRACT: This procedure specifies the standard method to be used to determine oil (hydrocarbon) contamination in compressed gases by the technique of dissolution in carbon tetrachloride. This procedure is to be used for pneumatic systems of space vehicles.

REVIEW: This is a mandatory specification outling in detail, and step-by-step, the procedure to be employed but is limited to pneumatic systems.
Note: Not breathing gases

AGENCY: NASA/MSFC

NUMBER: MSFC-PROC-166B REV: DATE: 17 July 1964

TITLE: Hydraulic System Components and Hydraulic Fluids for Space Vehicles, Cleaning, Testing, and Handling

ABSTRACT: This document specifies methods, materials, and equipment to be used in cleaning, testing, and handling of hydraulic system components and hydraulic fluids for use on board space vehicles and in supporting equipment (filter elements, actuators, pumps, power packages, accumulators, and tubing). It also includes requirements for environmental control and protection of work areas and equipment, pretest inspection, and tagging of cleaned and packaged components and assemblies.

REVIEW: This is a mandatory specification presenting detailed cleanliness requirements for hydraulic systems and hydraulic fluids. It is used as a controlling specification.

Reference No. 24

AGENCY: NASA/MSFC

NUMBER: MSFC-SPEC-237A REV: DATE: 24 January 1963

TITLE: Solvent, Precision Cleaning Agent

ABSTRACT: This specification covers the requirements for a solvent to be used as a precision cleaning agent (1, 1, 2 - trichloro - 1, 2, 2 - trifluoro-ethane). Quality assurance provisions and methods of evaluating the solvent are established.

REVIEW: This specification is intended to control the quality of a precision cleaning solvent useful for space vehicles, components, and associated equipment. The solvent may be used for spraying, flushing, vapor degreasing, and ultrasonics. It is especially useful in clean rooms as a test media in testing cleanliness of components.

AGENCY: USAF

NUMBER: T. O. 42C-1-8 REV: DATE: 9 December 1960

TITLE: Chemical Rust Remover

ABSTRACT: This technical manual provides general instructions for the removal of rust from ferrous metal parts by chemical means. The rust removing compounds are of acid and alkali type. They may be used to remove rust from vehicle parts, aircraft parts, castings, bulk or stored steel, hardware, bearings, missile parts and tubes, cylinders, and as a de-ruster before plating.

REVIEW: This document provides general instructions for removal of rust to achieve part cleanliness prior to painting or other coating. Cleanliness levels are not established. Critical or contamination sensitive parts will require additional cleaning to achieve the desired cleanliness level.

Reference No. 26

AGENCY: NASA/MSFC

NUMBER: Dwg. No. 10411901 REV: DATE: 12 September 1963

TITLE: Cleaning and Passivation of Bellows and Ducts, Procedure For

ABSTRACT: This document specifies the procedure to be used for pickling, cleaning, and passivating stainless steel bellows and ducts which do not require as high a cleanliness level as fuel, oxygen, hydraulic, or pneumatic systems (Visually clean).

REVIEW: The design activity will authorize the use of this specification. Proper implementation is the responsibility of the contractor. Parts prepared to this specification would not be used in a contamination sensitive area. Special handling is not required.

AGENCY: USAF

NUMBER: T. O. 42B6-1-1 (with supplements) REV: DATE: 20 April 1964

TITLE: Technical Manual: Quality Control of Oxygen Propellant Liquid Oxygen, Aviator's Liquid Breathing Oxygen, and Aviator's Gaseous Breathing Oxygen

ABSTRACT: This manual provides information for quality control of liquid oxygen used as missile propellant, and liquid and gaseous oxygen used for breathing. The quality control requirements and contamination level are different for each usage. This document explains the difference and the established controls and standards. Methods of control and testing procedures are included.

REVIEW: This document offers a comprehensive discussion on the properties and requirements of liquid and gaseous oxygen for propellant and breathing purposes. It has been prepared and coordinated with all Air Force activities, manufacturers, and users of liquid and gaseous oxygen and is considered to be authoritative and represent the state of the art.

Reference No. 28

AGENCY: Specialty Converting, Inc., South El Monte, California

NUMBER: REV: DATE:

TITLE: Solvent Wash Test Procedure (For Testing of Plastic Film Material)

ABSTRACT: This procedure outlines a method to determine the contamination level of plastic film as used in packaging. The procedure uses a solvent wash of the critical surface of the plastic film; filtration of the particulate contamination from the solvent liquid; and microscopic examination of the filter disc. The nonvolatile residue (hydrocarbon) content is then tested in accordance with NASA MSFC-SPEC-164 (difference in weight of residue from the evaporation of used and unused solvent).

REVIEW: This procedure defines a method for testing plastic packaging film for particulate contamination. The method outlined is considered realistic and practical and should yield satisfactory, accurate results. .The testing for nonvolatile residue is referred to MSFC-SPEC-164. It is believed that the method in accordance with MSFC-SPEC-164 should be outlined within this document in order to make it complete. This document does not establish cleanliness levels, only procedure.

AGENCY: Controlled Environment, Inc., Needham, Massachusetts

NUMBER: REV: DATE:

TITLE: Annual bibliography of information relating to (1) clean rooms and contamination control; (2) sampling and monitoring air in clean rooms

ABSTRACT: This is a pamphlet-type index published by a commercial supplier of clean room equipment. It is an extensive listing of titles and sources for the various papers, articles, books, and publications relating to the general subject of clean rooms and contamination control.

REVIEW: This is a listing of titles only. Sources for obtaining a particular publication are usually included in an abbreviated form.

Reference No. 30

AGENCY: NASA/MSFC

NUMBER: Dwg. No. 60B32086 REV: DATE: 26 August 1964

TITLE: Cleaning, Testing, and Handling of Hydraulic Systems, Components and Fluids

ABSTRACT: This document establishes the contamination control requirements for fluid power and thrust vector control system, components, and fluids (hydraulics). Cleanliness levels, methods of cleaning, testing, packaging, and handling are prescribed.

REVIEW: This document is similar in scope and requirements to the NASA/MSFC specification MSFC-PROC 166B for hydraulic systems and fluids. There are areas in this document that allow for violation of previously attained cleanliness (paragraph 5.1.1.4).

AGENCY: General Electric Company/Re-Entry Systems Department

NUMBER: Mariner B Entry Vehicle, Vol 1 Technical Study, pp. 6-1 to 6-22 REV: DATE: 26 November 1963

TITLE: Mariner B Sterlilization

ABSTRACT: This is an outline and discussion of the method used to sterilize the Mariner B Mars probe. Sterilization is accomplished by use of elevated temperatures and other selected means. Clean room or controlled environments are used throughout assembly and test as well as other special equipment. The sterilization program was developed to meet the requirement of the probability of one in ten-thousand of contaminating Mars with viable organisms.

REVIEW: This publication offers a guideline for spacecraft sterilization. The various considerations are identified and methods of accomplishing, assuring, and testing for sterilization are presented. This is not a specification or procedure but will be helpful in developing a particular requirement for the control of biological contamination.

Reference No. 32

AGENCY: NASA/MSFC

NUMBER: MSFC-STD-343 REV: DATE: 9 March 1965

TITLE: Preservation, Packaging, Packing, Handling, and Shipping of Space Vehicle Supplies and Associated Equipment, General Standard For

ABSTRACT: This standard is for use by MSFC and MSFC contractors and establishes the general preservation, packaging and handling techniques for space hardware. The materials, methods, and procedures are defined for different classes or types of hardware including tubes, fittings, control devices, and electronic hardware items. Marking and overpack methods are included. Various types and methods of packaging are assigned classifications.

REVIEW: This is a preliminary standard that currently covers the more common components. The standard will have more items added by the use of supplements. Detail information on precision packing is presented. There is no requirement for cleanliness of the package material. Tamperproof provisions and detail quality requirements are not presented.

AGENCY: NASA/KSC

NUMBER: KSC-C-123 REV: D DATE: 12 July 1965

TITLE: Cleanliness Levels, Cleaning, Protection and Inspection Procedures for Parts, Field Parts, Assemblies, Subsystems, and Systems for Pneumatic Use in Support Equipment

ABSTRACT: This specification established six cleanliness levels for various types of components and materials in various applications. The cleanliness levels are established in particle and fibre size and count (population) and condensable hydrocarbons in PPM. There are six different cleaning procedures described in detail. The cleaning solutions and process controls are described. Two test methods (solvent wash and gas flow) are specified. Quality control provisions for solutions, containers, and procedures are included.

REVIEW: This is a comprehensive specification on the total subject of cleaning. Its intended use is for pneumatic systems of support equipment for space vehicles; however, the information and procedures outlined will have many other applications.

Reference No. 34

AGENCY: DOD/MIL-STD

NUMBER: MIL-STD-1246 REV: MI DATE: 19 December 1962

TITLE: Degree of Cleanliness and Clean Room Requirements

ABSTRACT: This standard is intended to serve as a general guide for cleanliness and clean room requirements. The responsibility for selecting the clean room class is left to the design activity. Basic clean room construction and operation are presented in terms of the class 1, 2, 3, 4 system of classification. Types of cleaners and basic cleaning methods are discussed.

REVIEW: The classification system used in this standard is generally considered to be obsolete. The classification system per Fed-Std-209 is the generally accepted system.

AGENCY: Aerospace Industries Association
(formerly Aircraft Industries Association)

NUMBER: REV: 1 August 1961 DATE: 7 March 1960

TITLE: Handbook for Contamination Control of Liquid Rocket Propulsion Systems

ABSTRACT: This handbook is intended as a document to standardize the method for determining and assuring cleanliness of liquid rocket propulsion systems. It is to be used by personnel concerned with hardware cleanliness, cleaning procedures, inspection, packaging, preservation, and facilities as applicable to liquid rocket propulsion systems. The handbook establishes levels of cleanliness for the various hardware and service media. Methods and procedures for cleaning, testing, packaging, and inspection are presented. Facilities, quality control provisions, and materials are described.

REVIEW: This handbook presents a comprehensive detailed outline for the cleanliness requirements of liquid rocket propulsion systems. The major aerospace companies (14 in number) participated in the preparation of this handbook. It may be considered authoritative. The data is similar in coverage to AF T.O. 42C-1-11; however, additional detail information is included. Although this document was prepared for a specific purpose in a specific industry, the information will be useful in other contamination control applications.

Note: The cleanliness levels established for the various hardware and services do not agree with AF T.O. 42C-1-11 which is a more recently developed specification.

Reference No. 36

AGENCY: Society of Automotive Engineers/Aerospace Recommended Practice

NUMBER: ARP 785 REV: DATE: 2 February 1963

TITLE: Procedure for the Determination of Particulate Contamination in Hydraulic Fluids by the Control Filter Gravimetric Procedure

ABSTRACT: This document describes the procedure for determining the amount by weight of particulates in a sample of hydraulic fluid. The method described is to pass a quantity of fluid through two filter discs. The top disc retains the particulates, and the bottom disc is used as a control disc. A vacuum is applied to cause the fluid to flow through the discs. The discs are weighed before and after filtering to determine the amount of contaminants retained. The change in weight of the control disc indicates any adjustment necessary to compensate for changes in filter disc weight during the process.

REVIEW: This procedure is considered the standard method for determining the amount of contaminants by weight in hydraulic fluid. This is a test method only, the method for taking the sample is not described. This method is considered accurate within 0.2 mg per sample.

AGENCY: American Society for Testing and Materials

NUMBER: ASTM-F50-65T REV: DATE: 1965

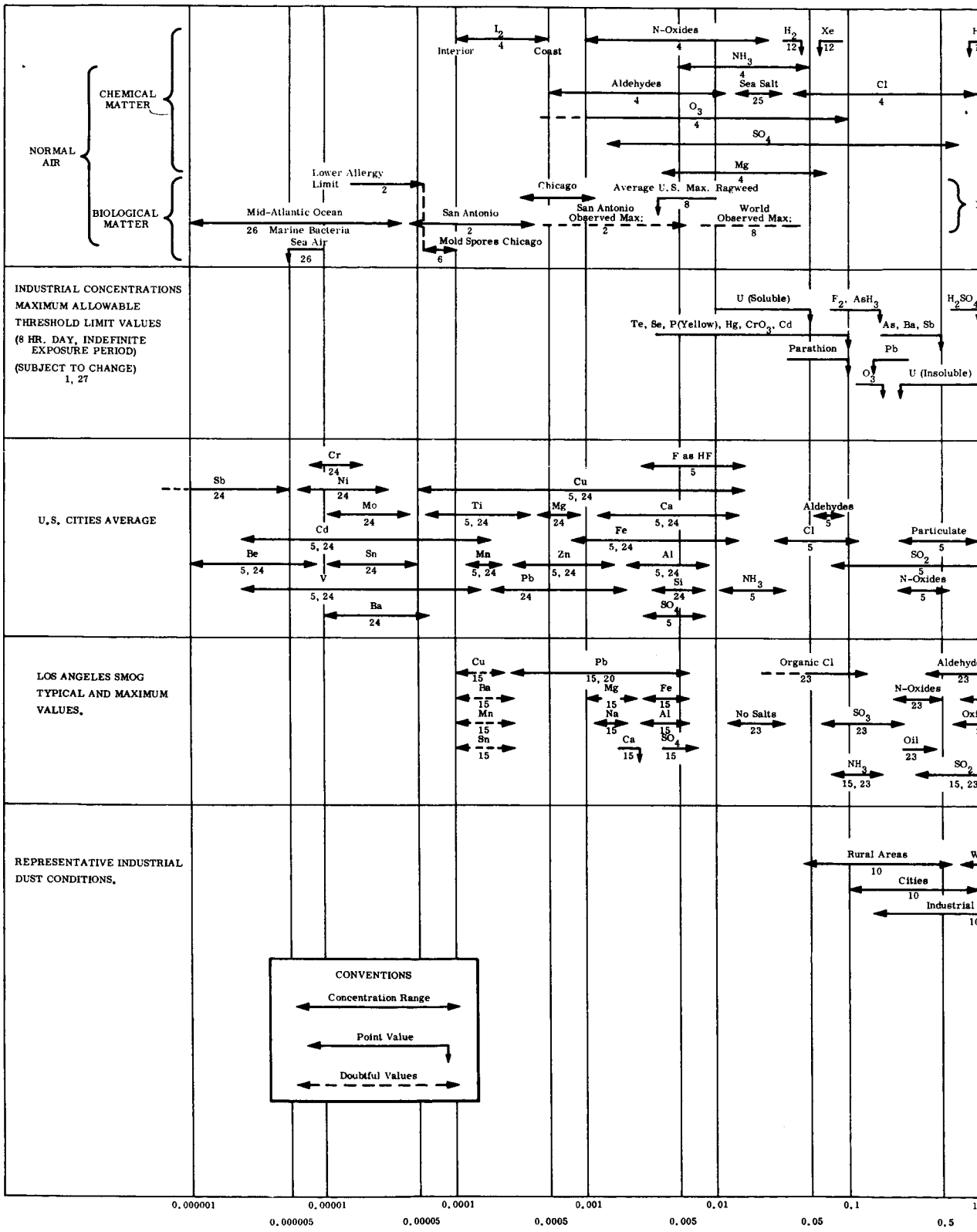
TITLE: Continuous Counting and Sizing of Airborne Particles in Dust-Controlled Areas by the Light Scattering Principle (for Electronic and Similar Applications)

ABSTRACT: This document describes the method for determining particle concentration and distribution for particles in the 0.5-to-5.0 micron range in dust controlled areas. Not applicable for particle concentrations exceeding 30,000 particles/liter, (1,000,000 particles/ft^3) 0.5 micron and larger. This method utilizes equipment which detects and sizes particles by the light scattering principle. The document refers to ASTM recommended practice D1357, for the recommended sampling plan.

REVIEW: This method is the most widely used automatic method for particle counting of clean room atmospheres. The method does not provide an absolute count, but only provides a relative measure of the particle concentration. A wide number of variables may affect the results and each factor must be specifically defined for consistency of results.

APPENDIX

CONTAMINATION DATA



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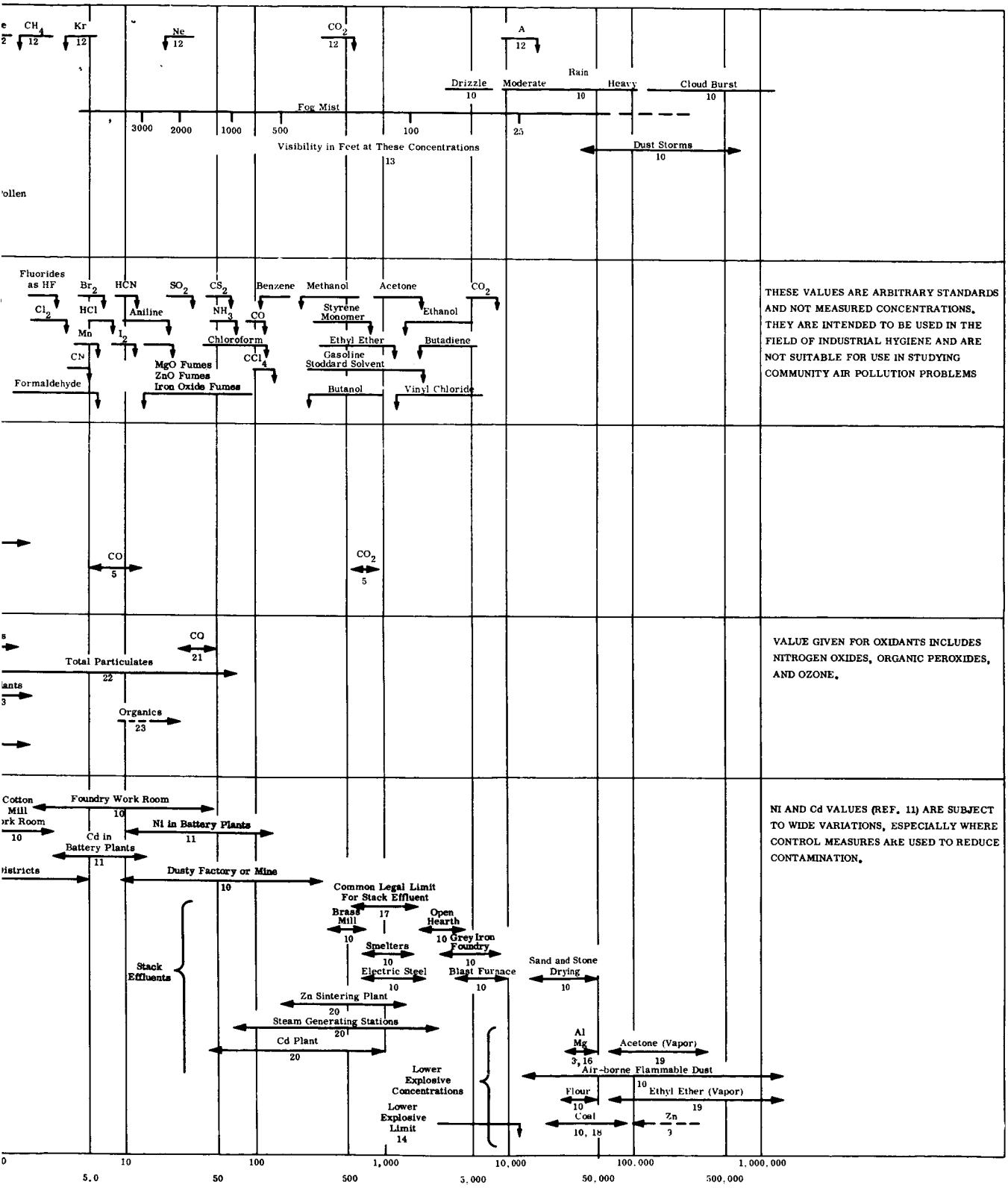
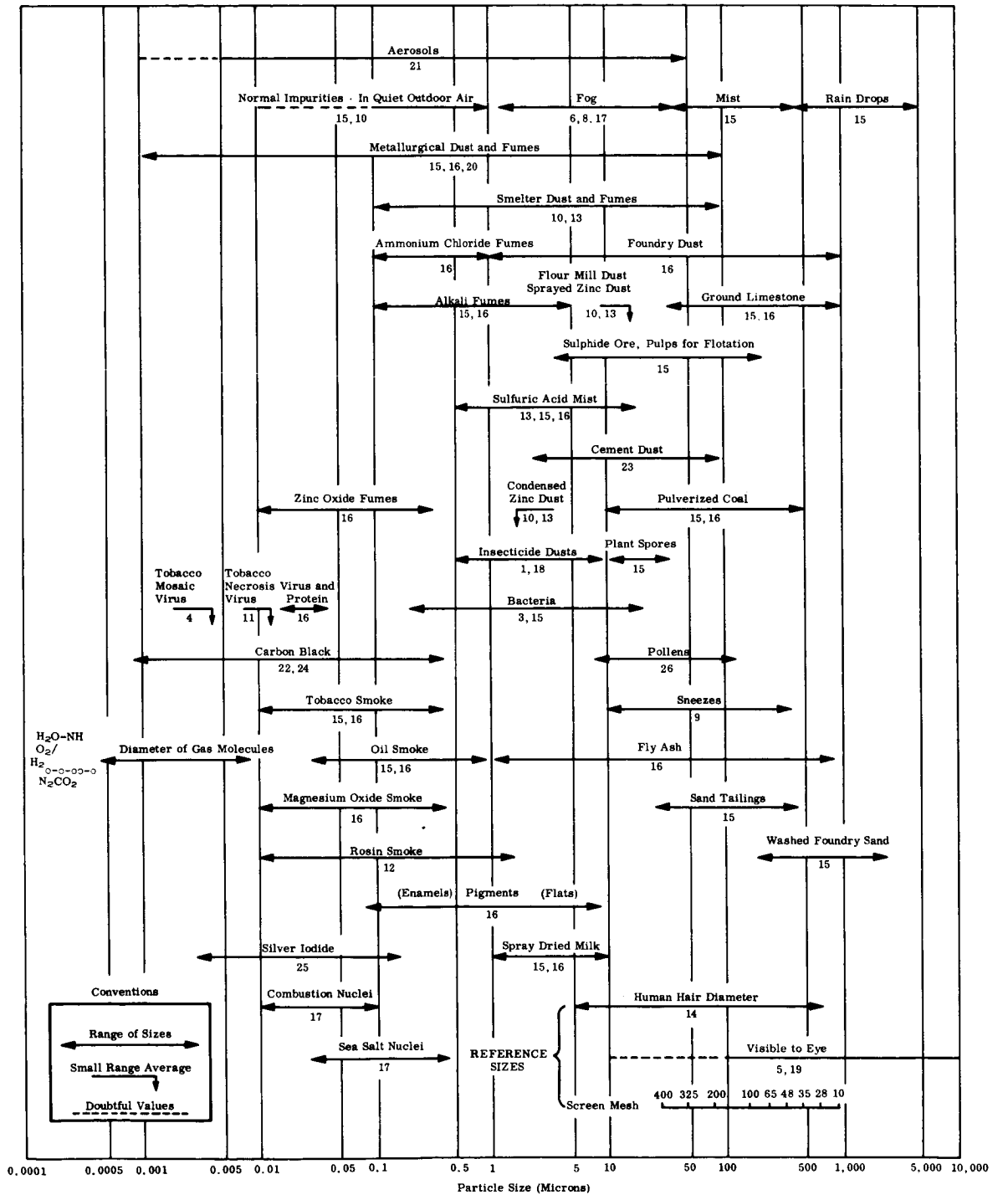
Concentrations - Milligram



Note: The Numbers Represent Bibliography References

Figure A-1. Concentrations of Materials in the Air



NOTE: The numbers represent bibliography references (Page B-6).

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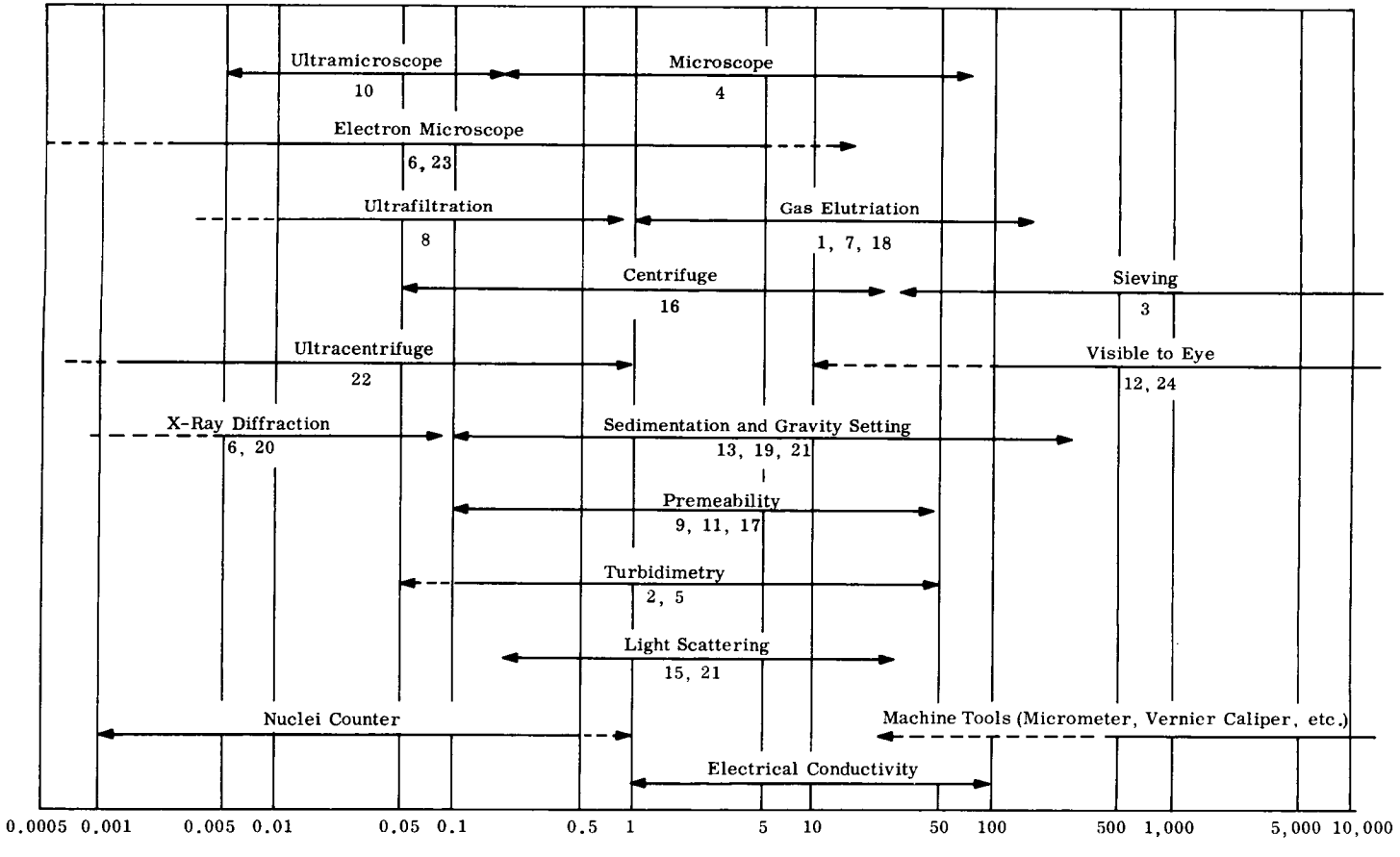
Figure A-2. Sizes of Airborne Contaminants



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NOTE: The Numbers Represent Bibliography References (Page B-9).

Variations in the Limits of Each Method Are Possible Depending on the Quality of the Instrument, Skill of the Operator, Etc.

Figure A-3. Limits of Particle Size Measuring Equipment

The following maximum allowable concentration values for continuous 8 hr. exposure are recommended by the American Conference of Governmental Industrial Hygienists and are revised when toxicological data warrants.

GASES AND VAPORS

Substance	PPM*
Acetaldehyde	200
Acetic acid	10
Acetic anhydride	5
Acetone	1,000
Acrolein	0.5
Acrylonitrile	20
Ammonia	100
Amyl acetate	200
Amyl alcohol (isoamyl alcohol)	100
Aniline	5
Arsine	0.05
Benzene (benzol)	35
Bromine	1
Butadiene (1,3-butadiene)	1,000
Butanone (methyl ethyl ketone)	250
Butyl acetate (n-butyl acetate)	200
Butyl alcohol (n-butanol)	100
Butyl cellosolve (2-butoxy-ethanol)	200
Carbon dioxide	5,000
Carbon disulfide	20
Carbon monoxide	100
Carbon tetrachloride	25
Cellosolve (2-ethoxyethanol)	200
Cellosolve acetate (hydroxy-ethyl acetate)	100
Chlorine	1
Chlorobenzene (monochloro-benzene)	75
Chloroform (trichloromethane)	100
1-Chloro-1-nitropropane	20
Chloroprene (1-chloro-butadiene)	25
Cresol (all isomers)	5
Cyclohexane	400
Cyclohexanol	100
Cyclohexanone	100
Cyclohexene	400
Cyclopropane	400
o-Dichlorobenzene	50
Dichlorodifluoromethane	1,000
1,1-Dichloroethane	100
1,2-Dichloroethylene	200
Dichloroethyl ether	15
Dichloromonofluoromethane	1,000
1,1-Dichloro-1-nitroethane	10
Dichlorotetrafluoroethane	1,000
Diethylamine	25
Dimethylaniline (N-dimethyl-aniline)	5
Dimethylsulfate	1
Dioxan (diethylene dioxide)	100
Ethyl acetate	400
Ethyl alcohol (ethanol)	1,000
Ethylemine	25
Ethyl benzene	200
Ethyl bromide	200
Ethyl chloride	1,000
Ethyl ether	400
Ethyl formate	100
Ethyl silicate	100
Ethylene chlorohydrin	5
Ethylene dibromide (1,2-dibro-moethane)	25
Ethylene dichloride (1,2-di-chloroethane)	100
Ethylene oxide	100
Fluorine	0.1
Fluorotrichloromethane	1,000
Formaldehyde	5
Gasoline	500
Heptane (n-heptane)	500
Hexane (n-hexane)	500
Hexanone (methyl butyl ketone)	100
Hexone (methyl isobutyl ketone)	100
Hydrogen chloride	5
Hydrogen cyanide	10
Hydrogen fluoride	3
Hydrogen selenide	0.05
Hydrogen sulfide	20
Iodine	1
Isophorone	25
Mesityl oxide	50
Methyl acetate	200
Methyl alcohol (methanol)	200
Methyl bromide	20
Methyl cellosolve (methoxy-ethanol)	25
Methyl cellosolve acetate (ethylene glycol monomethyl ether acetate)	25
Methyl chloride	100
Methylal (dimethoxymethane)	1,000
Methyl chloroform (1,1,1-trichloroethane)	500
Methylchlohexane	500
Methylcyclohexanol	100
Methylcyclohexanone	100
Methyl formate	100
Methylene chloride (dichloro-methane)	500
Naphtha (coal tar)	200
Naphtha (petroleum)	500
Nickel carbonyl	0.001
Nitrobenzene	1
Nitroethane	100
Nitrogen dioxide	5
Nitroglycerin	0.5
Nitromethane	100
2-Nitropropane	50
Nitrotoluene	5
Octane	500
Ozone	0.1
Pentane	1,000
Pentanone (methyl propyl ketone)	200
Perchlorethylene (tetra-chloroethylene)	200
Phenol	5
Phosgene (carbonyl chloride)	1
Phosphine	0.05
Phosphorus trichloride	0.5
Propyl acetate	200
Propyl alcohol (isopropyl alcohol)	400
Propyl ether (isopropyl ether)	500
Propylene dichloride (1,2-dichloropropane)	75
Stibine	0.1
Stoddard solvent	500
Styrene monomer (phenyl ethylene)	200
Sulfur monochloride	1
Sulfur dioxide	10
1,1,2,2-Tetrachloroethane	5
Toluene	200
o-Toluidine	5
Trichloroethylene	200
Turpentine	100
Vinyl chloride (chloroethene)	500
Xylene	200

TOXIC DUSTS, FUMES, AND MISTS

Substance	Mg. Per Cu. M†
Antimony	0.5
Arsenic	0.5
Barium (soluble compounds)	0.5
Cadmium	0.1
Chlorodiphenyl	1
Chromic acid and Chromates as CrO_3	0.1
Cyanide as CN	5
Dinitrotoluene	1.5
Dinitro-o-cresol	0.2
Fluoride	2.5
Iron oxide fume	15
Lead	0.15
Magnesium oxide fume	15
Manganese	6
Mercury	0.1
Parathion (0,0-Diethyl-0-p-nitrophenyl thiophosphate)	0.1
Pentachloronaphthalene	0.5
Pentrachlorophenol	0.5
Phosphorus (yellow)	0.1
Phosphorus pentrachloride	1
Phosphorus pentasulfide	1
Selenium compounds (as Se)	0.1
Sulfuric acid	1
Tellurium	0.1
Tetryl (2,4,6-trinitrophenyl-methylnitramine)	1.5
Trichloronaphthalene	5
Trinitrotoluene	1.5
Uranium (soluble compounds)	0.05
Uranium (insoluble compounds)	0.25
Zinc oxide fumes (as Zn)	15

Radioactivity: For permissible concentrations of radioisotopes in air see "Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water," Handbook 52, U. S. Department of Commerce, National Bureau of Standards, March 1953. In addition, see "Permissible Dose from External Sources of Ionizing Radiation," Handbook 59, Department of Commerce, National Bureau of Standards, September 24, 1954.

MINERAL DUSTS

Substance	MPPCF‡
Alundum (aluminum oxide)	50
Asbestos	5
Carborundum (silicon carbide)	50
Dust (nuisance, no free silica)	50
Mica (below 5% free silica)	20
Portland Cement	50
Silica	
high (above 50% free SiO_2)	5
medium (5 to 50% free SiO_2)	20
low (below 5% free SiO_2)	50
Slate (below 5% free SiO_2)	50
Soapstone (below 5% free SiO_2)	20
Talc	20
Total dust (below 5% free SiO_2)	50

*Parts of vapor or gas per million parts of air, by volume.

†Milligrams of dust, fume, or mist per cubic meter of air.

‡Millions of particles per cubic foot of air.

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Figure A-4. Toxicity of Contaminants - Maximum Allowable Concentrations

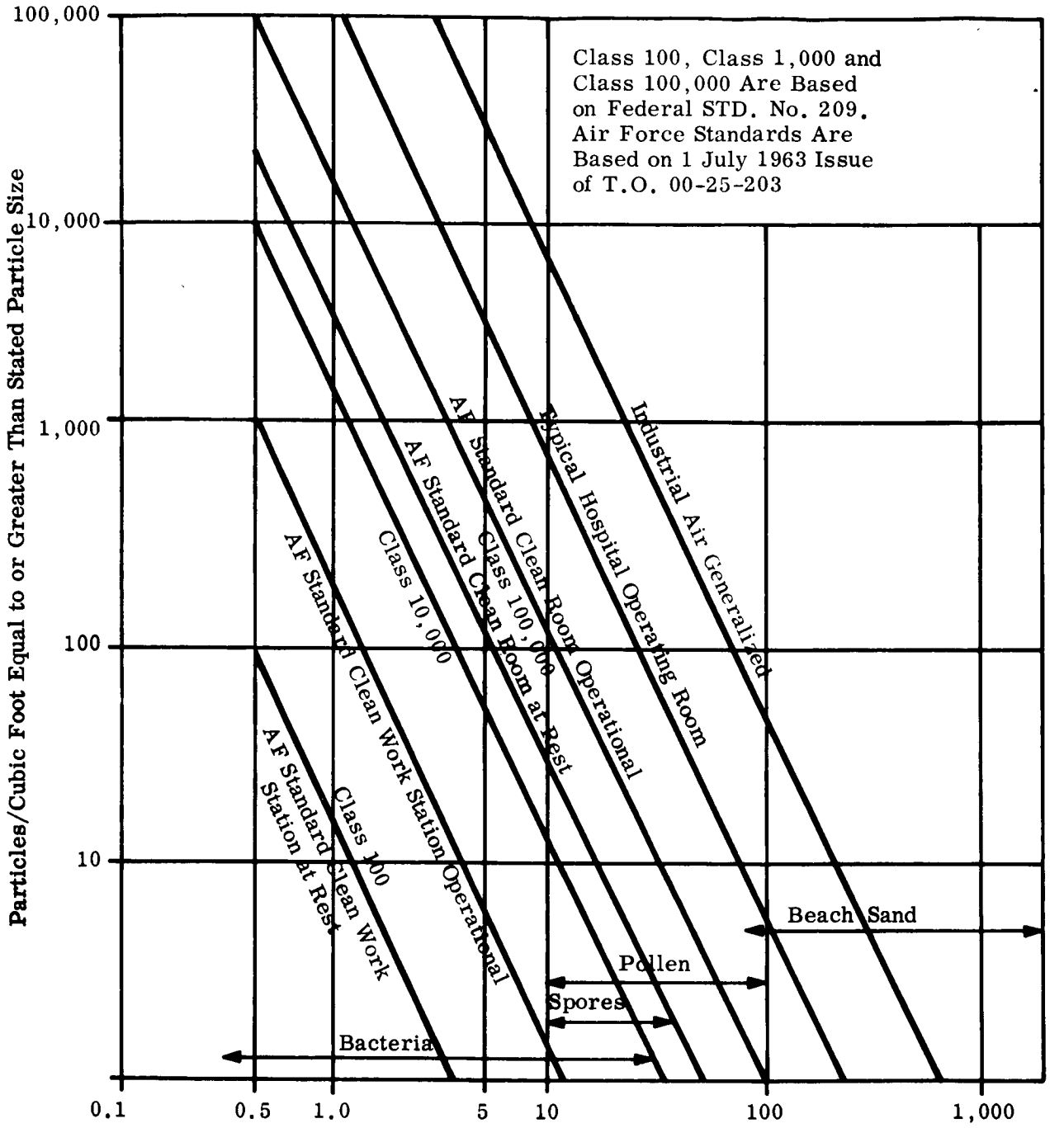
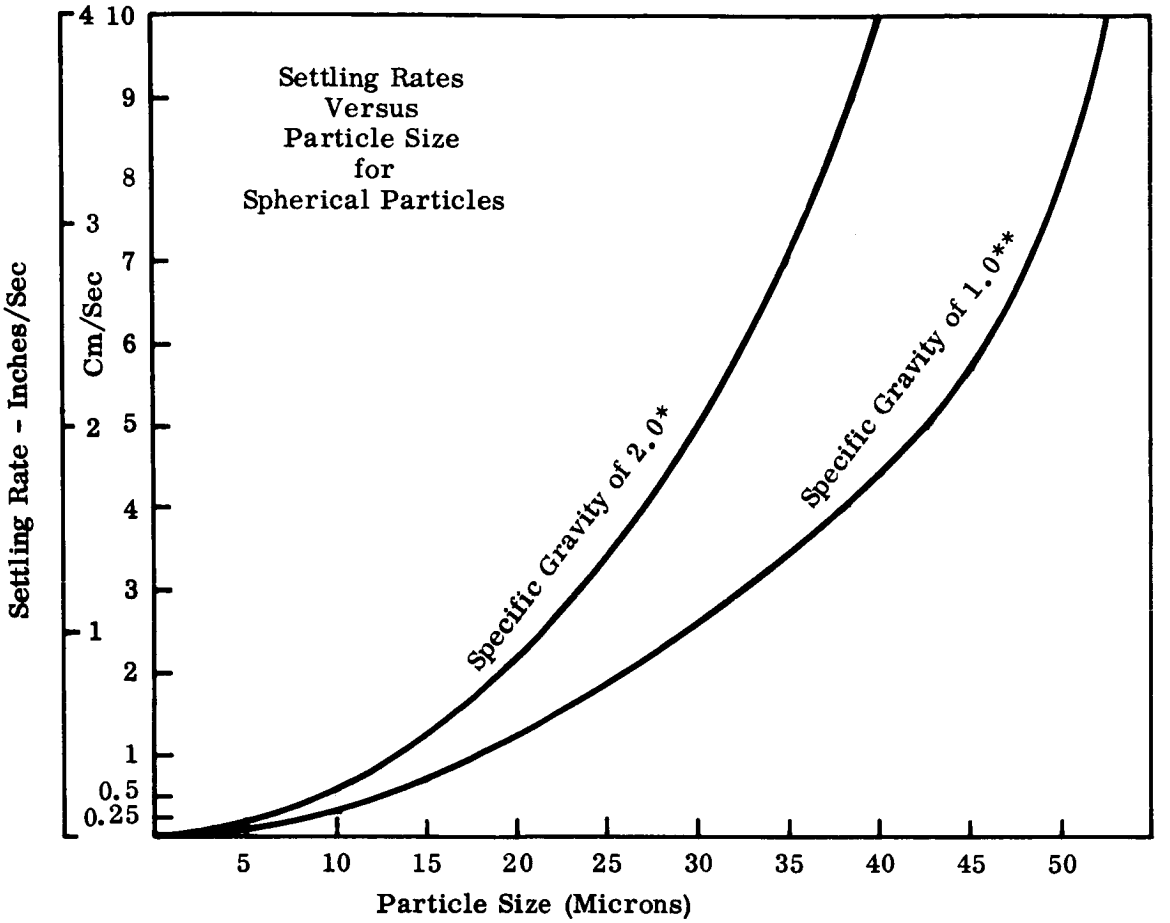


Figure A-5. Comparison Among Various Classes of Clean Rooms and Clean Work Stations



Diameter of Particles (Microns)	Velocity of Settling**		
	Feet per Minute	Inches per Hour	Centimeters per Hour
0.1	0.00016	0.115	0.292
0.2	0.00036	0.259	0.658
0.4	0.0013	0.936	2.35
0.6	0.002	1.44	3.66
0.8	0.005	3.60	9.15
1.0	0.007	5.04	12.7
2.0	0.024	17.3	44.0
4.0	0.095	68.4	174.0

*Taken from SCTM-131-61(25) "Dust Monitoring in Clean Rooms" August 1961, by Sandia Corporation for U. S. Atomic Energy Commission. Rates are for particles in the shape of spheres having a specific gravity of 2.0.

**Compiled from "Size and Characteristics of Airborne Solids," by W. G. Frank, published in the Smithsonian Meteorological Tables. Rates are for particles in the shape of spheres, having a specific gravity of 1.0 and settling in air at a temperature of 70°F.

Figure A-6. Settling Rates for Airborne Particles

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BIBLIOGRAPHY

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